

A New Method for Capture Detection in the Right Atrium

L. HUDSON, C. LESSARD

Department of Biomedical Engineering, Texas A&M University, College Station, Texas, USA

M. MILLER, S. GORDON

Michael E. DeBakey Institute, College of Veterinary Medicine, Texas A&M University, College Station, Texas, USA

Summary

A method has been developed for performing capture detection in the right atrium using the same electrode for pacing and sensing. The method of capture detection senses the occurrence of an atrial evoked response. A custom pacing and sensing system under PC control was used to test the capture detection method. The new method uses a pacing pulse similar to a standard pulse but does not use an active charge balancing pulse, such as a triphasic pulse. The capture detection system verifies the occurrence of an atrial evoked response during a programmable capture detection window. The system was tested in four dogs. A test pacing sequence was used to collect data on confirmed capture and non-capture beats. For each animal tested, capture detection was performed with greater than 99% sensitivity and 99% specificity. The results of these tests show the feasibility of detecting capture in the right atrium from the same pacing and sensing electrode without the use of an active charge balancing pacing pulse.

Key Words

Atrial evoked response, capture detection

Introduction

A reliable method of capture detection using evoked response in the right atrium has been a technical challenge. The life of a pacemaker device could be extended if the pacing stimulus amplitude were much smaller than the recommended 100% margin over the threshold voltage [1]. Beat-by-beat detection would allow the pacemaker to deliver a safety pace, guaranteeing capture if the stimulus threshold exceeds the programmed pace pulse amplitude. Several methods of capture detection are currently in use for ventricular pacing, but atrial capture detection has been difficult due to lead and signal characteristics.

One major problem encountered is the masking of the atrial evoked response by polarization voltage after a pace delivery. Several methods have been proposed to overcome this problem. Livingston et al. used unipolar pacing with unipolar sensing of the evoked response from the

ring electrode [2]. Guyomar et al. used a device with a 15 ms blanking time with unipolar pacing and bipolar sensing (St. Jude Medical, USA). In this study, detection was only possible in 55% of patients studied [3]. Vonk et al. used a triphasic waveform to actively balance the charges which occur after a pace pulse delivery [4]. Curtis et al. also used a triphasic pacing waveform [5]. The above methods either pace and sense from the different electrodes or require the use of some type of active charge balancing waveforms. The active charge balancing methods effectively double the pacing current due to the pacing waveform characteristics. Even if the delivered voltage is slightly above the stimulation threshold, the pacing current is nearly the same as a standard pace pulse with a 100% margin. A method of capture detection with the ability to pace and sense from the same electrode using a standard style pacing pulse is highly desirable.

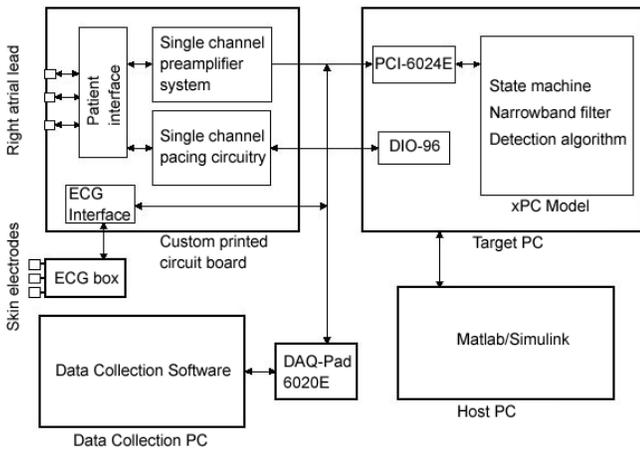


Figure 1. Detection and data collection system.

Materials and Methods

System

A system was developed to provide a simulated single channel pacemaker (Figure 1). A custom printed circuit board contained the pacing circuit and a wide-band preamplifier system. The wide-band preamplifier system had a frequency response of 0.2 – 180 Hz and was capable of various gain settings, the most used being 100 and 1000. This preamplifier system was designed to minimize the effects of unblanking with a DC offset at its input. The pacing circuitry was capable of programmable pulse amplitudes to -10.0 V and pulse widths as small as 0.1 ms with 0.1 ms increments. A Matlab/Simulink/xPC model (MathWorks, USA) running on a target computer performed all further filtering and threshold detection functions. A lap-

top computer acted as host computer controlling the Matlab/Simulink/xPC model and allowed programming of various parameters during operation. A custom surface ECG system was included in the system, and a second laptop computer collected and stored all data.

Animals

Four mongrel dogs of either sex were used to study the system. All animal studies were approved by the Texas A&M University Laboratory Animal Care Committee (ULACC). Animals were anesthetized with butorphanol (0.2 – 0.4 mg/kg intramuscular) and propofol (4 – 6 mg/kg intravenous), intubated and ventilated with 0.25% – 2% isoflurane. A femoral artery catheter and skin electrodes were placed for continuous monitoring of blood pressure and cardiac rhythm, respectively. The right jugular vein was surgically exposed, and through a 3 – 6 cm veinotomy a Elox 45 BP pacing lead (Biotronik, Germany) was advanced into the heart. This electrode was advanced under fluoroscopic guidance and implanted in the right atrium.

The implantable data block was inserted in a pocket formed under the skin near the exposed jugular vein. Data acquisition equipment was then attached to the data block via a cable and needle electrodes. Bolus injections of Diltiazem (2.5 mg) were given at regular intervals when required to keep the intrinsic heart rate below 95 beats/min. Procainamide (25 – 50 mg/kg/min) was administered intravenously to minimize atrial fibrillation. Data was then collected for various programmable settings, and at the end of the procedure the animals were sacrificed humanely.

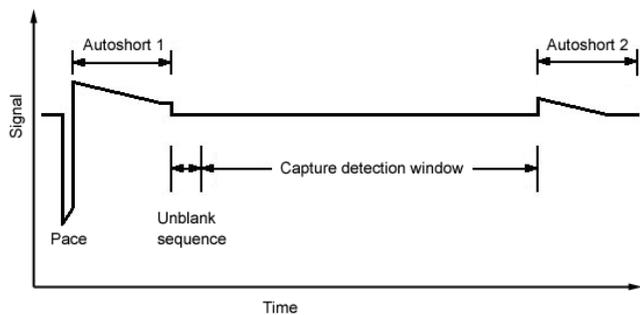


Figure 2. Determining the presence of an evoked response using a modified standard pacing pulse sequence.

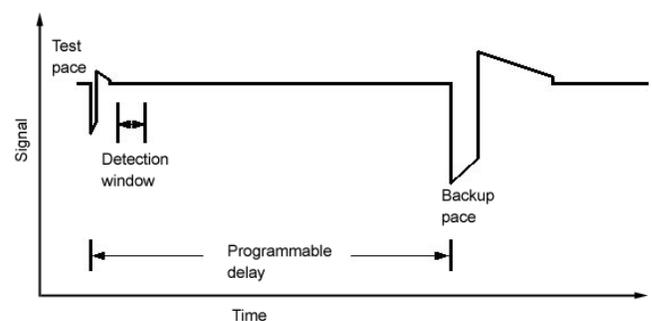


Figure 3. Test pulse sequence.

	Canine 1	Canine 2	Canine 3	Canine 4
Pacing rate (pulses/min)	100	105	105	105
Pacing amplitude (V)	-1.0	-1.0	-0.8	-0.5
Pulse width (ms)	0.1	0.1	0.3	0.2
Autoshort time (ms)	4	4	1	2
Capture window length (ms)	15	25	20	15
Backup pulse amplitude (V)	1.5	1.5	-1.5	-1.5
Backup pulse width (ms)	1	1.5	0.2	0.5
Backup pulse delay (ms)	100	100	90	80
Threshold voltage (V)	-0.7	-1.0	-1.0	-1.0
Pre-amplifier gain	1000	1000	1000	1000

Table 1. Programmed parameters for capture only data.

Methodology

The method of determining the presence of an evoked response used a modified standard pacing pulse sequence (Figure 2). A programmable monophasic pulse was delivered followed by a programmable autoshort period (autoshort 1), which was shorter than the time between the end of the pace pulse and the first negative peak of an evoked response signal. After the first autoshort period, the wide-band preamplifier began the unblank sequence. At the end of the 1.0 ms unblank sequence, a programmable capture detection window was invoked to sense the beginning portion of the evoked response. At the end of the capture detection window the preamplifier was again blanked and a second programmable autoshort (autoshort 2) was performed to insure charge neutrality over the entire pacing cycle.

The test pulse sequence (Figure 3) was used to test the detection method and create files of true capture and true non-capture. The test pulse sequence added a backup pace to the modified pacing sequence to collect non-capture data as well as ensure a pacing rate that was above the intrinsic heart rate. The backup pace amplitude and width were set above the stimulation threshold and the delay between the test pulse and the backup pacing pulse was programmable.

	Canine 1	Canine 2	Canine 3	Canine 4
Pacing rate (pulses/min)	100	105	105	105
Pacing amplitude (V)	-0.4	-0.6	-0.8	-0.4
Pulse width (ms)	0.1	0.1	0.1	0.1
Autoshort time (ms)	4	4	1	2
Capture window length (ms)	15	25	20	15
Backup pulse amplitude (V)	1.5	1.5	-1.5	-1.5
Backup pulse width (ms)	1	1.5	0.2	0.5
Backup pulse delay (ms)	100	100	80	80
Threshold voltage (V)	-0.7	-1.0	-1.0	-1.0
Pre-amplifier gain	1000	1000	1000	1000

Table 2. Programmed parameters for non-capture only data.

For true capture files, the test pulse was adjusted to ensure that it caused a depolarization of the atrial tissue. Autoshort 1 time was adjusted to allow the negative peak of the evoked response signal to be observed, and the capture detection window width set to include the entire negative peak seen by the wide-band preamplifier from the end of autoshort 1 to when the signal crosses zero. The detection level was set to approximately one-half the value of the negative peak of the evoked response. For corresponding true non-capture files, the detection levels were unchanged. The test pulse was adjusted to be below the stimulation threshold for these files. The true capture data file recordings contain the output of the wide-band preamplifier, the output of the narrow-band filter, an ECG signal, a pace pulse marker, and a capture detected marker. The true non-capture data files contain the same information. Each file was analyzed to determine the total number of true signals occurring and the resulting system analysis. Any instances of atrial flutter or fibrillation were excluded from the data sets. All fusion beats, intrinsic signals occurring just before the pacing pulse, were also excluded from data set analysis.

We calculated the 99.9% confidence intervals of sensitivity and sensitivity for each animal. The analogous p-value < 0.001 was considered statistically significant.

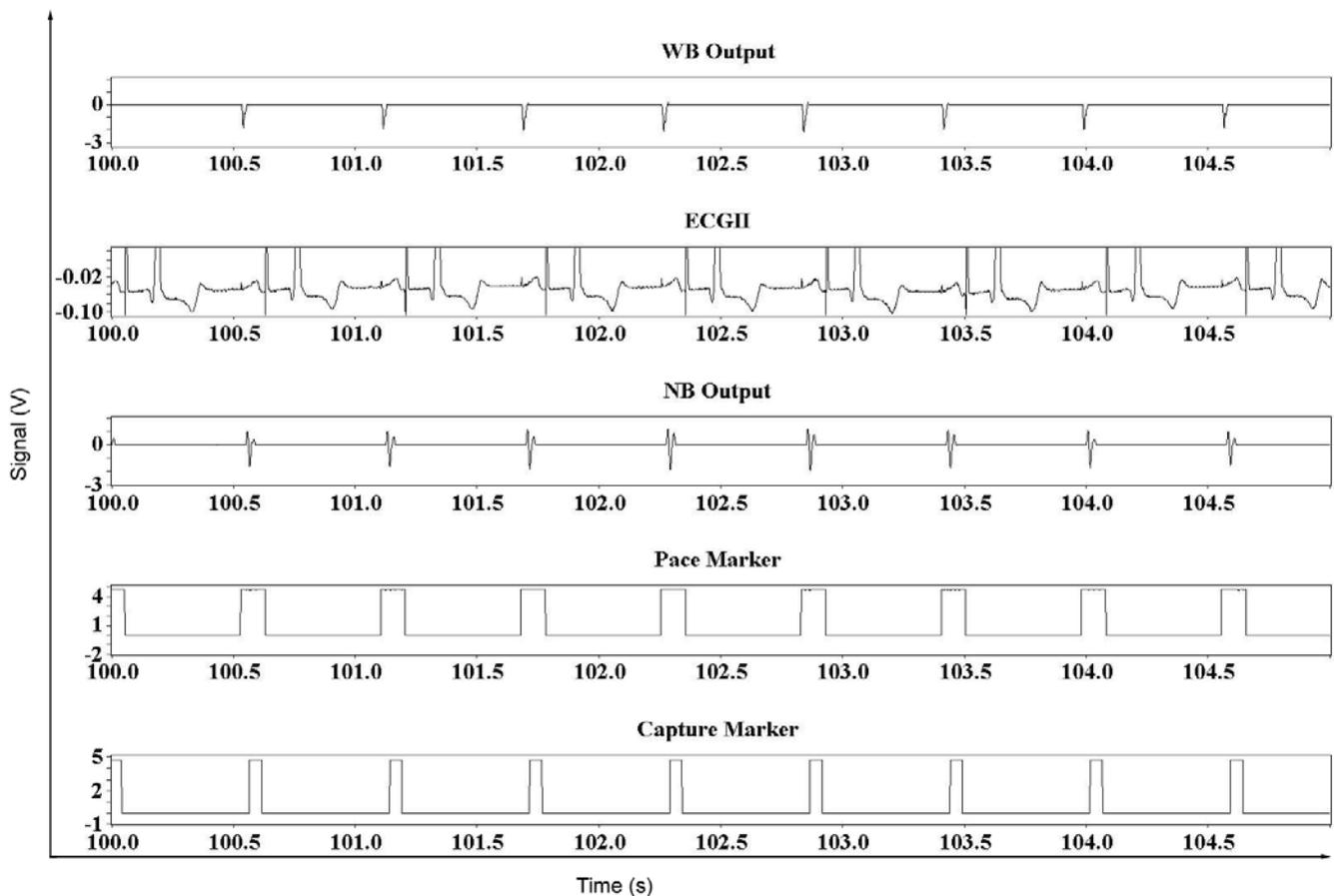


Figure 4. Sample of stored data of capture file from canine 2. NB = narrow-band filter, WB = wide-band filter.

Results

Table 1 shows the programmed parameters of the system for the capture data obtained from each animal. The test pulse amplitude and pulse width were adjusted to assure capture by the system. Table 2 shows the programmed parameters of the system for non-capture data obtained from each animal. The test pulse amplitude and width were adjusted to assure capture on the backup pulse. The detection threshold voltage was unchanged from the corresponding capture file parameters.

Figure 4 shows a sample of data collected from canine 2 of true capture signals. In the ECG channel, the small pulse immediately before the P-wave is the test pulse, the large spike at the end of the P-wave is the backup pace. Each test pulse in this figure is followed by a P-wave denoting true capture. The wide-band output (WB Output) is the output of the wide-band preamplifier and shows the evoked response during the capture detection window. The narrow band

output (NB Output) is the output of the narrow-band filter on which the detection level is set. The pace marker shows the timing of the test pulse and the backup pulse, the rising edges denote the beginning of the test pulse, the falling edges denote the beginning of the backup pulse.

Figure 5 shows a sample of data collected from canine 2 of true non-capture signals. In the ECG channel, the large spike at the beginning of the P-wave is the backup pace. Each backup pulse in this figure is followed by a P-wave denoting true non-capture. The wide-band output (WB Output) is the output of the wide-band preamplifier and shows the evoked response during the capture detection window. The narrow band output (NB Output) is the output of the narrow-band filter on which the detection level is set. The detection threshold was unchanged from the capture data settings, in this case the detection level was -1.0 V. The detection level was applied to the narrow-band output.

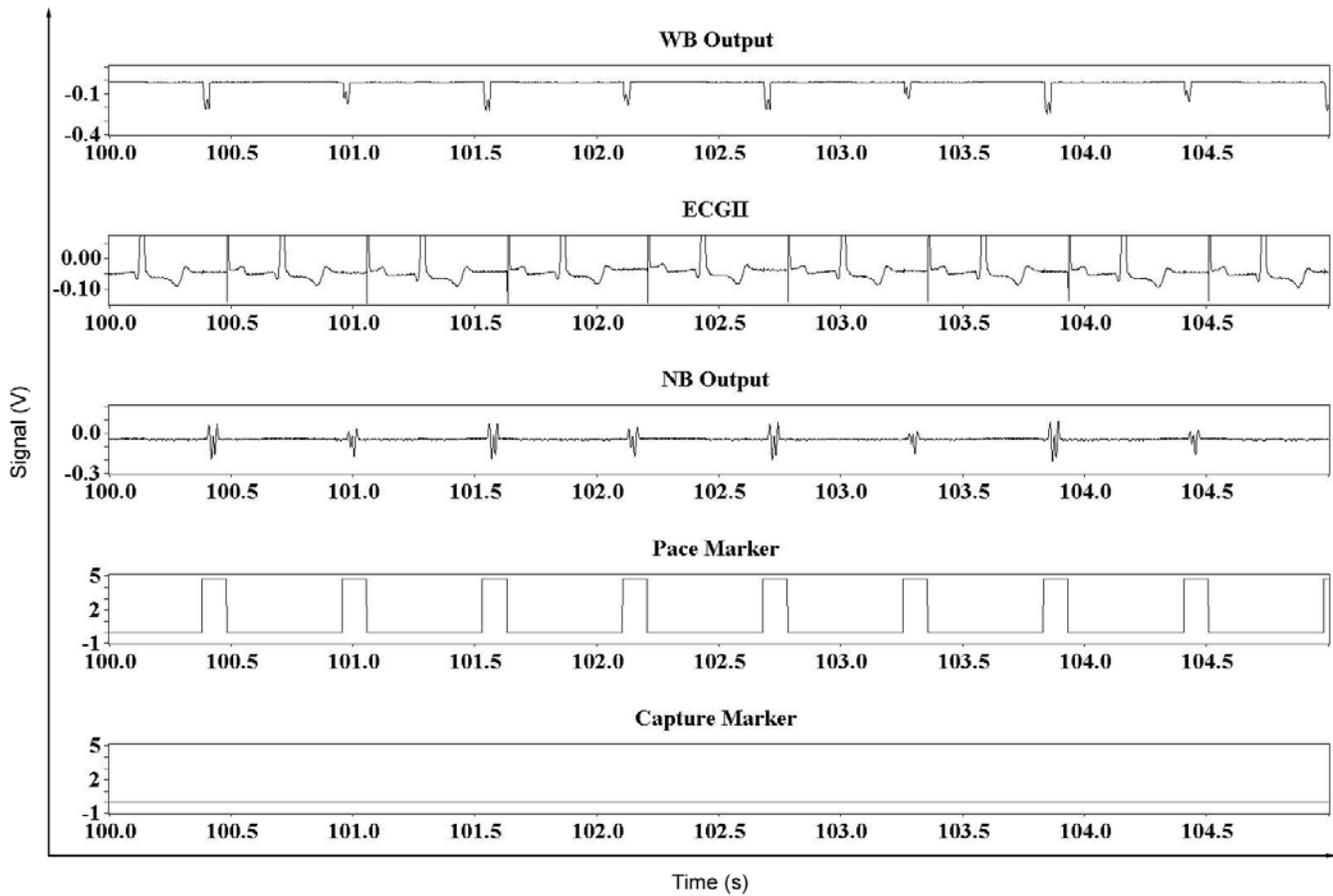


Figure 5. Sample of data from non-capture file from canine 2. NB = narrow-band filter, WB = wide-band filter.

Table 3 shows the total number of system classifications for true capture signals for each animal. Table 4 shows the total number of system classifications for true non-capture signals for each animal. Tables 5 – 8 show the sensitivity and specificity of the system for each animal based on the 99.9% confidence intervals on the means of each data set. Thereby, sensi-

tivity is defined as the number of true captures classified as capture and specificity as the number of true non-captures classified as non-capture. By using the lowest value of the 99.9%-confidence interval, sensitivity > 99.7% and specificity > 99.7% of the capture detection system has been shown for all animals with a significance level of p-value < 0.001.

	System classification for true capture	
	Capture	Non-capture
Canine 1	6759	0
Canine 2	3242	0
Canine 3	4004	0
Canine 4	3243	0
Total	17258	0

Table 3. System classification totals for true capture signals.

	System classification for true non-capture	
	Capture	Non-capture
Canine 1	0	3760
Canine 2	0	3212
Canine 3	0	3632
Canine 4	0	5005
Total	0	15609

Table 4. System classification totals for true non-capture signals.

	Capture	Non-capture
True capture	(0.9989, 1.0000)	(0.0000, 0.0011)
True non-capture	(0.0000, 0.0020)	(0.9980, 1.0000)

Table 5. Contingency table of true capture detection versus capture detection by the new method presented as 99.9% confidence intervals for canine 1.

	Capture	Non-capture
True capture	(0.9977, 1.0000)	(0.0000, 0.0023)
True non-capture	(0.0000, 0.0024)	(0.9976, 1.0000)

Table 6. Contingency table of true capture detection versus capture detection by the new method presented as 99.9% confidence intervals for canine 2.

	Capture	Non-capture
True capture	(0.9981, 1.0000)	(0.0000, 0.0019)
True non-capture	(0.0000, 0.0021)	(0.9979, 1.0000)

Table 7. Contingency table of true capture detection versus capture detection by the new method presented as 99.9% confidence intervals for canine 3.

	Capture	Non-capture
True capture	(0.9977, 1.0000)	(0.0000, 0.0023)
True non-capture	(0.0000, 0.0015)	(0.9985, 1.0000)

Table 8. Contingency table of true capture detection versus capture detection by the new method presented as 99.9% confidence intervals for canine 4.

Discussion

Detecting the right atrial evoked response has been difficult due to afterpotentials and the signal characteristics of the evoked response. Most approaches use some type of active charge balance pacing waveform to overcome these challenges. This study tested the feasibility of pacing and sensing from the same elec-

trode using a standard style pacing pulse. The system included a new preamplifier design which enables sensing to begin much closer to the pace pulse than previous designs. For each animal the programmable parameters could be adjusted to distinguish capture versus non-capture. Autoshort 1 time, capture detection window width, and detection level could be adjusted to sense the beginning of the right atrial evoked response in each canine. The characteristics of the wide-band preamplifier allowed the detection portion of the system to begin sensing the evoked response very soon after the application of a large stimulus pulse. The lead type chosen minimized residual polarization after the pacing pulse due to its high Helmholtz capacitance, as well as the iridium oxide covered indifferent electrode. All of these characteristics of the system account for the high degree of sensitivity and specificity.

Over 17,000 true captures and 15,000 non-captures were analyzed with no misclassifications by the system. Each statistical test resulted in p-values of 1 due to the absence of misclassifications. Confidence intervals on sensitivity and specificity were calculated for 99.9% intervals, and for each animal the lower interval bound for sensitivity and specificity was a minimum of 99.76%. These values were used to calculate the remaining portions of the sensitivity/specificity tables. Based on the results from the four animals, the method has less than a 0.24% chance of misclassifying a non-capture as a capture. This statistic is very important for systems performing beat-to-beat analysis that supplies a safety pace in the event of a non-capture. Under the test conditions specified, the system met the study goal of greater than 99% sensitivity and specificity for right atrial capture detection. These results show the ability to perform capture detection in the right atrium using the same electrode for both pacing and sensing without the use of a true charge balancing waveform, such as a triphasic waveform. The ultimate goal of any capture detection system is to be implemented in an implantable device with low power consumption and very high reliability. This study represents one of the first steps in the design of a reliable right atrial capture detection system for pacemakers.

There are several items to be studied in more detail with this capture detection system. The indifferent electrode used for this study was coated with a material similar to the coating on the electrodes. Only one

type of implantable electrode was used in this study, and each animal had low pacing thresholds. Many different electrodes might potentially be used with this system and these different styles must be studied with the system to determine their effect on evoked response recognition. The leads were also implanted at the time of the study, so all data reflect the system performance for the acute phase of lead implantation, especially for pacing thresholds. Pacing at much higher thresholds must be investigated. The system should be studied on chronically implanted leads to find any differences between the acute and chronic evoked response.

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Contact

Dr. Lee Hudson
Department of Biomedical Engineering
Texas A&M University
3120 TAMU
College Station, Texas 77843-3120
USA
Fax: +1 979 845 4450
E-mail: hudsonl@msei-tx.com