

Enhanced Software Based Detection of Implanted Cardiac Pacemaker Stimuli

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Abstract

With increasing use and sophistication of implantable cardiac pacemaker devices, new techniques are required to ensure accurate detection of pacemaker stimuli. This study aimed to (i) compare the accuracy of enhanced pacemaker spike detection logic using 32,000 samples/sec (sps) data against existing software based on current AAMI/IEC standards; (ii) assess the ability of the new logic to aid in the detection of biventricular (BiV) pacing; (iii) develop and test a method for the detection of BiV pacing based on QRS morphology. 72 patients were recruited. 63 were used to assess spike detection accuracy and 62 to assess the accuracy of reporting BiV pacing. 33/62 had BiV pacemakers. 9 patients were excluded for various reasons. The new logic improved accuracy of spike detection from 46/63 to 62/63. For BiV pacing, the new logic had a sensitivity of 97% and a specificity of 100% while the QRS morphology logic had a sensitivity of 70% and a specificity of 93%.

1. Introduction

An implanted cardiac pacemaker is a device that applies repeated electrical stimulation to the heart muscle at a desired rate. A standard dual chamber pacemaker would have one lead in the right atrium and another in the right ventricle (RV) at the apex.

Biventricular (BiV) pacemakers are capable of pacing both the right and left ventricles as well as the right atrium. The left ventricular (LV) lead is placed inside a cardiac vein, against the free wall of the left ventricle. BiV pacemakers help restore synchrony of ventricular contraction, which can be lost when the heart dilates in severe heart failure. This treatment is called cardiac resynchronisation therapy (CRT) and is associated with enhanced survival in patients with severe heart failure[1].

Each year, over 40,000 cardiac devices are implanted in the UK [2]. This has led to a need for improved reporting of ECGs from patients with these devices [3].

Standard ECG machines, like the Burdick Atria 6100, sample the ECG signal at 500 samples per second (sps), i.e. every 2ms. A pacemaker stimulus lasts 0.2ms, and

may therefore not be reliably detected. The Atria 6100 is capable of sampling at 64 kilo-sps (ksps) for internal usage or 32 ksps, i.e. every 0.03ms, for exporting data from two leads. Thus, such a device could make 16 measurements of a typical 0.5ms stimulus, which would aid in its detection.

The mean QRS axis is a measure of the direction of ventricular depolarization, which can be affected by changes to the sequence by a ventricular pacemaker [4].

It has been suggested that the ECG trace of a BiV pacemaker can be distinguished from that of an RV pacemaker [5]. The latter produces a pattern similar to that of LBBB and results in a predominantly positive QRS in lead I and negative QRS in leads III and V1. It has also been suggested that BiV pacing results in a cardiac axis directed towards the right superior quadrant of the frontal plane. It therefore may be possible to develop logic that can differentiate between the two different types of pacing using QRS morphology.

A previous study [6] assessed the accuracy of pacemaker detection in the Atria 6100, produced by Cardiac Science Corporation (CSC), compared with an older generation ECG machine. It showed that the Atria 6100 improved spike detection and could detect two separate ventricular stimuli in BiV pacing when programmed to operate at 32 ksps in two leads. As a result, new improved spike detection logic designed for data sampled at 32 ksps has been developed by CSC.

The primary aim of the present study was to compare the accuracy of detecting pacemaker activity using the current Atria 6100 spike detection logic versus the new logic. As the latter was not yet in an ECG machine, for the purposes of this study it was run externally on a PC. The second aim was to assess the accuracy of detecting BiV pacing using the new logic [9]. The third aim was to develop and assess the sensitivity and specificity of logic to report BiV pacing using QRS morphology.

2. Methods

2.1. Participants

Patients with implanted cardiac pacemakers were

invited to participate in the study at routine follow-up appointments at the relevant outpatient clinics, or when in hospital following pacemaker implantation at Glasgow Royal Infirmary between January and March 2009. Participants were excluded if they were deemed not well enough to take part. They were also excluded from the BiV arm of the study if they did not have active ventricular pacing. Written informed consent was obtained for each participant before entry into the study. Information regarding the manufacturer, mode and type of pacing of the implanted pacemaker device was gathered from participants' medical records.

2.2. Accuracy of pacemaker reporting

A 12-lead resting ECG was recorded for each participant using the standard settings (500 sps) of the Atria 6100. This ECG was printed and the automated analysis noted [7]. Once the original ECGs were sent to the ECG management system, the analysed files were downloaded to reveal a list of the exact location of each pacemaker spike on the 10-second ECG.

The Atria 6100 was also programmed to sample at 32 ksp/s in leads II and V4. These data were subsequently transferred to a PC. The files were then analysed using the new spike detection logic and a list of the pacemaker spikes detected was then produced.

The ability to detect a paced beat correctly was assessed. To be deemed "accurate", at least one spike for each atrial or ventricular paced beat needed to be detected. If, when analysing a BiV pacemaker, the new logic detected two ventricular spikes, only the first spike signifying the onset of ventricular depolarisation was used for this part of the study. Note that the interval between ventricular stimuli (V-V) may be zero. To be classed as "inaccurate", the logic must have failed to detect at least one spike for a single paced beat, or incorrectly reported a pacing spike, e.g. due to noise.

2.3. QRS morphology logic

To develop the QRS morphology logic for the reporting of BiV pacing, the data from a previous study [6] were used as a training set. In total, 16 participants in the training set had a BiV pacemaker. The QRS complexes from each lead of every ECG in the training set were given a code based on the QRS morphology. The QRS duration and axis were also noted. Once suitable logic to detect BiV pacing was identified using the training set, it was evaluated on the test set ECGs.

2.4. Biventricular pacing

The sensitivity and specificity of the new spike detection logic and the QRS morphology criteria were determined using the test set. By referring to the spike list

produced by the new logic, it was possible to determine if BiV pacing had been detected. Plots were produced from the data generated by the new logic (Figure 1). If two spikes were recorded within 50ms of each other, they were deemed to be two ventricular spikes [8].

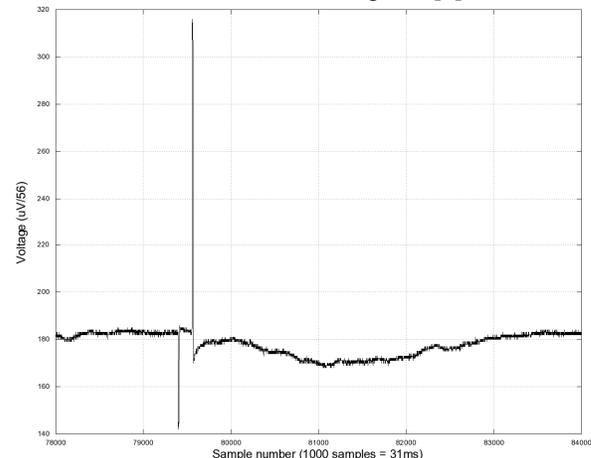


Figure 1. Example of two ventricular pacing spikes detected by new spike detection logic.

To determine the best method for the detection of BiV pacing, four combinations were compared. These were:

- the new spike detection logic on its own
- the QRS morphology logic on its own
- the new spike detection logic and the QRS morphology logic together
- either the new spike detection logic or the QRS morphology logic being positive

2.5. Statistical analysis

To minimise error during the data collection phase, a strict protocol for ECG measurement was maintained. Measurements were carried out by one researcher to avoid inter-observer variability, following a clear stepwise study protocol to minimise intra-observer variability. One ECG machine was used, to minimise inter-machine variability.

As this study looked at the difference in accuracy of two different tests on the same patients, the data were paired. To compare the accuracy of spike detection, the difference in proportions for paired data and a McNemar's Test with continuity correction were carried out. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for BiV pacing for each method used to detect BiV pacing were calculated. Confidence intervals (CIs) were calculated.

3. Results

72 patients were recruited to the study between January and March 2009. Nine patients were excluded

because five had no pacemaker activity during measurement, and in four patients high speed files were incorrectly recorded. In addition, one patient had to be excluded from the BiV pacing analysis arm as he had atrial pacemaker activity only. Of the 63 patients analysed, one had an atrial pacemaker, 29 patients had a pacemaker that paced the RV and 33 patients had a BiV pacemaker (32 BiV pacemakers had non-zero V-V and 1 had zero V-V interval). The baseline characteristics for all the patients analysed are summarised in Table 1.

Table 1. Baseline characteristics of patients.

	Spike Detection (n = 63)	Biventricular Pacing (n = 62)
Sex: Male	49 (78%)	48 (77%)
Female	14 (22%)	14 (23%)
Age: Mean ± SD	66.1 ± 11.4	66.0 ± 11.5
Pacemaker:		
Biventricular	33 (52%)	33 (53%)
CRT-P	11 (33%)	11 (33%)
CRT-D	22 (67%)	22 (67%)
Right Ventricular	29 (46%)	29 (47%)
Atrial	1 (2%)	-
DDD	1 (100%)	-

3.1. Accuracy of spike detection

In the analysis of accuracy of spike detection arm of the study, the Atria 6100 accurately detected pacemaker spikes in 46/63 (73%) ECGs. The new logic accurately detected pacemaker spikes in 62/63 (98%) ECGs. There was an increase in the probability of accurately detecting pacemakers spikes of 25% (95% CI, 13% to 37%) when using the new spike detection logic compared to the older Atria 6100 spike detection logic. McNemar’s test with continuity correction was used to assess the results in Table 2. This showed that there was a significant difference in the accuracy of the new spike detection logic against the old spike detection logic (P<0.001).

Table 2. Spike detection accuracy.

Logic		New spike detection		Total
		Accurate	Inaccurate	
Atria 6100 spike detection	Accurate	46	0	46
	Inaccurate	16	1	17
Total		62	1	63

3.2. Development of biventricular pacing QRS morphology

Analysis of QRS morphology of the ECGs from the training set resulted in the production of logic that was

56.25% sensitive and 100% specific for BiV pacing in the training set. The logic stated that a predominantly negative QRS in lead I or a QRS axis between -90° and -180°, would be characteristic of BiV pacing (Figure 2).

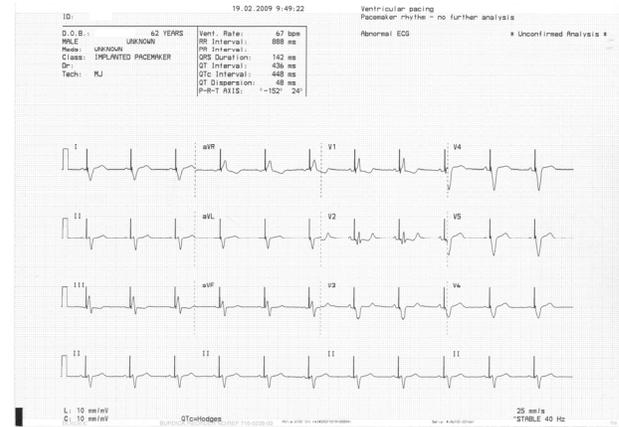


Figure 2 Example of an ECG that meets the criteria for BiV pacing based on QRS morphology.

3.3. Biventricular pacing

The new spike detection logic detected two closely spaced ventricular pacing spikes, and therefore BiV pacing, in 32/33 of the ECGs from patients with BiV pacemakers, and did not produce any false positive results. It therefore had a sensitivity of 97%, a specificity of 100%, a positive predictive value (PPV) of 100% and a negative predictive value (NPV) of 97%. The logic based on the QRS morphology correctly identified 23/33 of the ECGs from patients with BiV pacemakers. However, it produced a positive result for two non-BiV pacemakers. It therefore had a sensitivity of 70%, a specificity of 93%, a PPV of 92% and a NPV of 73%. The combination stating that both the new spike detection logic and the QRS logic must be positive to indicate BiV pacing detected 23/33 of the BiV pacemakers and no false positives. It had a sensitivity of 70%, a specificity of 100%, a PPV of 100% and a NPV of 74%. The combination requiring either the new spike detection logic or the QRS logic to be positive to report BiV pacing picked up 32/33 BiV pacemakers correctly and two non-BiV pacemakers incorrectly. It had a sensitivity of 97%, a specificity of 93%, a PPV of 94% and a NPV of 96%.

4. Discussion and conclusions

The results from this study clearly show that the new spike detection logic using a sampling rate of 32 ksp/s significantly improves the accuracy of spike detection in patients with implanted cardiac pacemakers. In addition, it is able to accurately detect BiV pacing with an

excellent degree of sensitivity and specificity. The logic for the detection of BiV pacemakers based on the QRS morphology of an ECG may also be a useful tool for the detection of BiV pacing in less sophisticated ECG machines or for manual ECG reporting.

4.1. Accuracy of spike detection

The results show that the new spike detection logic using 32 ksp data is significantly more accurate than that in the Atria 6100 based on current AAMI/IEC standards. The 95% CI suggests that the increase in accuracy could be between 13% and 37%, with a best estimate of 25%. As well as being statistically significant, these results are also clinically significant, and will lead to greater accuracy in automated reporting of pacemaker activity.

4.2. Biventricular pacing

The results suggest that the new spike detection logic is of benefit for detecting BiV pacing. It had a sensitivity and specificity superior to that of the QRS logic and any combination of the new spike detection and QRS logic.

Often the factory setting of a BiV pacemaker is a V-V interval of zero, which remains after implantation. The initial reason for the development of diagnostic logic for BiV pacing based on QRS morphology was to detect BiV pacing if the new spike detection software failed, or if V-V were 0. In this study, only one patient had no time delay. As expected, only one ventricular pacing spike was detected by the new logic. However, BiV pacing was also not detected by the QRS logic and so this was the only BiV pacemaker that was not detected by either type of logic. It is possible that the LV pacing lead was not functioning properly.

However, it may be the case that the QRS logic does not detect BiV pacing when V-V is zero. Details of the time intervals between the two ventricular stimuli for patients in the training set, from which this logic was developed [6], were not available, and so it was not possible to identify any patients with V-V of zero. Further study of the QRS morphology of patients with V-V of zero is recommended to enhance BiV detection.

Despite the accuracy of QRS logic for BiV pacing being less than that of the spike logic, it is still useful. The QRS logic has an excellent specificity and a high sensitivity, so it can be used independently of the new spike detection logic which requires a sampling rate of 32 ksp. The QRS logic could be put into a less sophisticated ECG machine, or used directly to diagnose BiV pacing.

4.3. Study limitations

This study has a number of limitations. There is a large variation in types of pacemaker and this study has a small sample size. This has meant that there was little subgroup

analysis of the effect of different programming modes of pacing on accuracy of detection. There are still questions unanswered with regard to BiV pacing when V-V is zero.

The two ECG recordings taken were not obtained simultaneously. This means that the same beats are not present in both of the recordings, and so spike detection accuracy was not measured on the same spikes.

A limitation to the use of the QRS morphology logic to detect BiV pacing is that there is a great deal of variation in the site at which the left ventricular pacing lead is placed. This means that it is difficult for any QRS morphology logic for BiV pacing to be 100% sensitive.

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