# Comparison of P Wave Durations as Assessed with the Bipolar and Unipolar Atrial Intracardiac Electrograms: Applicability to QuickOpt™

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**Abstract**

*Studies have shown that inter-atrial conduction time (IACT) can be used to estimate optimal PV delays. QuickOpt utilizes the atrial EGM (AEGM) and measures P-wave duration (PW) to estimate the IACT. This study compares PW between bipolar (Bi) and unipolar (Uni) AEGMs in patients with either a pacemaker (PP) or a CRT-D pulse generator. Bipolar (Bi) and Unipolar (Uni) AEGMs were obtained from 42 PP and 18 CRT-D pts. In the PP, PWs associated with Bi and Uni AEGMs were close (114±19 ms vs. 110±20 ms). Intra-patient difference was 3.9±8.7 ms, and the 95% confidence interval for the difference was (1.2, 6.6). With CRT-D, PWs were 79±18.4 ms and 81±14 ms for Bi and Uni sensing and the intra-patient difference was -1.2±14.9 ms. In 18 PP, the difference between ECG and either bipolar or unipolar PW was 4.8±17.8 ms and 0.9 ms ± 15.5 ms respectively. PWs were similar between unipolar AEGMs, bipolar AEGMs, and surface ECG.*

## 1. Introduction

Cardiac resynchronization therapy is intended to treat pharmacologically refractory HF in patients with mechanical dyssynchrony involving the left ventricle. Cardiac synchrony can be restored by controlling the timing and sequence of atrial and bi-ventricular stimulation. Despite continual enhancements in CRT therapy, about 1/3 of patients fail to improve at the manufacturers' default settings. Possible explanations for these "non-responders" include ventricular leads in a suboptimal position, inappropriate atrio-ventricular timing (AV) or intraventricular timing (VV), loss of LV capture, absence of dyssynchrony (mechanical and/or electrical), and ischemic burden/tissue vitality.

Currently, the "gold standards" for programming the AV and VV delays are echocardiography (Echo) and Echo/Tissue Doppler Imaging (TDI), respectively. Echo is expensive and time-consuming, and reimbursement may not sufficiently cover costs of repeated Echo studies to assess and guide CRT programming. It has been estimated that only 10% of CRT patients receive echo optimizations on a routine basis; frequently, its use is limited to those individuals who do not respond to the shipped or physician-prescribed settings. Recently St. Jude Medical (SJM) introduced a programmer-based algorithm (QuickOpt™), utilizing the intracardiac electrogram (IEGM) and conduction intervals, that provides a quick, efficient and effective method for interval optimization that compares favorably with echo/TDI methods.

QuickOpt utilizes IEGM signals in novel ways to estimate the optimal AV/PV and VV delays. The IEGM-based AV/PV delay method is an empirical method resulting from clinical observations. A marked intra-atrial conduction delay is common in HF patients due to mitral valve regurgitation or/and a dilated left atrium. A nominal AV/PV delay setting can cause such patients to suffer from symptoms similar to those of pacemaker syndrome, while adjusting the AV or PV delay for a longer duration, allowing the left atrial depolarization to complete before ventricular activation, may relieve these symptoms. The IEGM-based VV delay is based on the hypothesis that at the optimal VV delay, paced depolarization wavefronts initiated by both the RV and LV leads will achieve better electrical synchrony, leading to better mechanical synchrony in the majority of patients. The IEGM-CRT clinical study in over fifty subjects [1] demonstrated that the echo-Doppler derived aortic velocity integral (AVTI) values at the QuickOpt-predicted AV, PV, and VV delays were linearly correlated with maximum AVTI, with Concordance Correlation Co-efficients (CCC) of 97.5%, 96.1% and 96.6% respectively. A retrospective analysis of data from SJM's RHYTHM study, where the VV intervals were optimized in sixty-one patients [2] also showed strong Concordance Correlation Co-efficient (CCC) =99%. Additional analysis of VV delays [3] was done retrospectively in the combined RHYTHM VV and IEGM-CRT patient cohorts. QuickOpt-recommended VV delays produced significantly greater mean AVTI values than those with simultaneous biventricular pacing. The difference in AVTI values between maximum AVTI and AVTI at QuickOpt-recommended settings was significantly smaller than the variations in AVTI within patients over a range of VV delays.

QuickOpt suggested PV/AV delays are based on inter-atrial conduction time (IACT). Published studies have shown that inter-atrial conduction time (IACT) measured at a mid-CS electrode can be used to estimate echo-optimal PV delays [4]. It is also known that surface ECG P wave durations have been used by physicians as a surrogate for IACT. Because the implantable systems typically have only a single atrial lead, positioned in the right atrium (RA), QuickOpt utilizes the atrial EGM (AEGM) from the RA lead and measures P wave duration to estimate the IACT (Figure 1).

Implantable systems may include unipolar or bipolar atrial leads. Unipolar leads have only a single electrode (cathode) on the lead body itself; a remote electrode (on another lead, or the metal housing of the implantable device) serves as the anode. In contrast, bipolar electrodes incorporate both cathode and anode on the lead body. In addition, systems with bipolar leads can often be non-invasively programmed to allow sensing to occur in either a bipolar or a unipolar configuration. Because unipolar sensing involves a wider dipole than does bipolar sensing, the EGM obtained from it may contain more far field information. The potential difference in the duration of atrial bipolar and unipolar signals, which, if significant, could affect the calculations made by the QuickOpt algorithm, has not been thoroughly examined. This study compares differences in P wave duration between bipolar and unipolar atrial sensing configurations in patients with standard pacemaker and CRT-D systems, as well as differences between the bipolar, unipolar configurations and the P waves on a surface ECG in a subset of these patients.

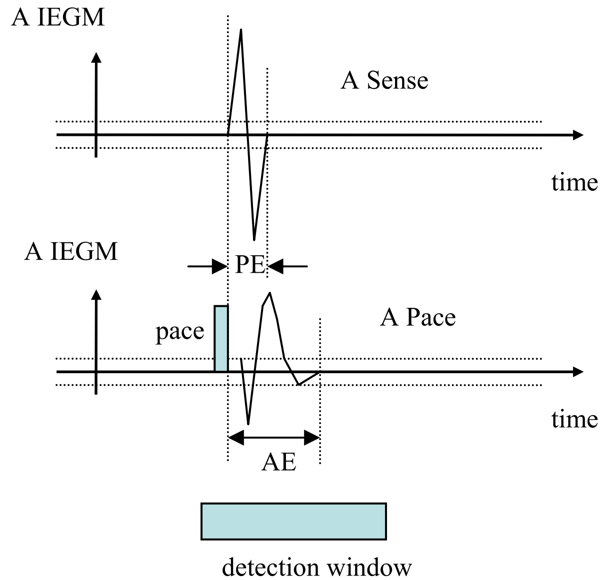


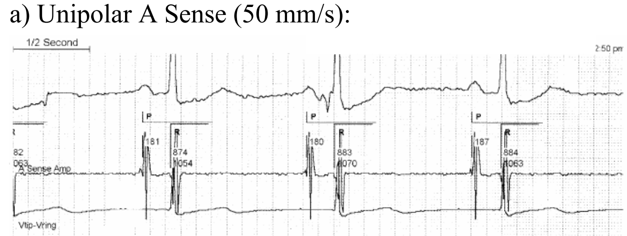

Figure 1: QuickOpt PV and AV Delays

## 2. Methods

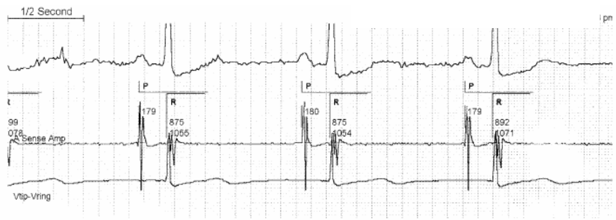
Bipolar and unipolar AEGMs were obtained from 42 pacemaker patients and analyzed for P wave duration. All the pacer patients had SJM pacing leads with tip-to-ring electrode spacing (TRS) of 10-13 mm. The paired bipolar and unipolar atrial sensed signals from SENSE/PACE channels were measured manually by a single engineer, and the baseline (i.e., resting potentials) of these signals was used to define the P wave duration. Measurable surface ECG signals were also obtained and included in the analysis. An example of the signals for bipolar, unipolar and surface ECG is shown in Figure 2. The reported values represent the average measurements over three beats.

Figure 2: An example of bipolar, unipolar and surface ECG signals from a pacemaker patient.

a) Unipolar A Sense (50 mm/s):




b) Bipolar A Sense (50 mm/s):




Similar data was collected from 18 CRT-D patients implanted with SJM Epic/Atlas systems which included SJM leads with conventional TRS. QuickOpt "A sense" tests were used to measure bipolar and unipolar P wave durations automatically. Unipolar atrial signals were fed through a test setup to run the QuickOpt "A sense" tests. The "A sense" tests used an internal threshold of 0.2 mV to determine the beginning of P wave at a sensed event; the algorithm declared the end of P wave when three consecutive points fell below 0.2 mV. The reported P wave duration was the mean over 8 consecutive beats. The time resolution of these signals was 8 ms. Surface ECG signals were not available from the 18 CRT-D patients.

## 3. Results

In the pacemaker group, mean P wave durations of the unipolar and bipolar AEGMs were very close (114 ± 19 ms vs. 110 ± 20 ms ). The mean intra-patient difference was 3.9 ms ± 8.7 ms, and 95% confidence intervals for the mean difference were (1.2, 6.6) ms, which is within pre-specified criteria of 10 ms. Only 3 out of 42 pts had a bipolar P wave duration greater than that of unipolar P wave. The ranges of the durations were from 78 ms to 150 ms for unipolar, and from 71 ms to 140 ms for bipolar signals. In the CRT-D patients, mean P wave durations were 79 ms ±18.4 ms for unipolar and 81 ms ±14 ms for bipolar sensing. The mean intra-patient difference was -1.2 ms ± 14.9 ms, and 95% confidence intervals for the mean difference were (-9.1, 6.8) ms, which is also within 10 ms. The ranges were from 50 ms to 105 ms for unipolar, and from 52 ms to 107 ms for bipolar sensing. Ten of the 18 CRT-D patients had bipolar P wave duration greater than that of unipolar P wave. In 18 of the 42 pacemaker patients, the surface ECG P waves were available. The difference between ECG and bipolar P waves was 5.1 ms ± 18.3 ms (ranges: 80-150 ms; 80-140 ms), and the 95% confidence intervals for the mean difference were (-4, 14.2) ms. The difference between ECG and unipolar P waves was 0.9 ms ± 15.5 ms (ranges: 80-150 ms; 80-150 ms), and the 95% confidence intervals for the mean difference were (-6.8, 8.6) ms. Only 3 out of 18 patients had bipolar P wave durations greater than ECG P wave durations.

## 4. Discussion and conclusions

One would expect that the P wave duration on the surface ECG (most far-field content) would provide the best estimate of IACT, followed by the unipolar atrial EGM (moderate far-field content), and finally by the bipolar atrial EGM (least far-field content). However, in a pilot animal study that preceded the study reported here, involving seven canines, it was found that the P wave duration as measured on the ECG was almost identical with the unipolar atrial EGM, with a ratio of 0.99±0.04. Moreover, the results of this study, comparing the unipolar and bipolar AEGM durations in 42 pacemaker and 18 CRT-D patients, and with the surface ECG P wave duration in 18 pacemaker patients, showed that either the unipolar or bipolar AEGM could serve as a reasonable surrogate for estimating IACT. Although atrial leads with the same TRS were implanted in both the pacemaker and CRT-D groups, the unipolar AEGM duration in the pacemaker patients was, as expected, slightly greater than the bipolar AEGM duration, while the same directional consistency was not noted in the CRT-D patients probably due to the difference in device filters. However, the differences between the unipolar and bipolar AEGM P wave durations were small enough to render the noted inconsistency clinically unimportant. Further analysis may elucidate its cause.

The measured P wave duration in an algorithm like QuickOpt may vary as a result of the lead system from which the AEGMs are obtained. Factors such as unipolar vs. bipolar electrode configuration, as well as the spacing of the electrodes on a bipolar lead [5], may affect the degree to which far-field left atrial signals are detected. Some newer leads, such as the SJM OptiSense™ lead, incorporate very closely spaced (1.1 mm TRS) bipolar electrodes specifically intended to avoid sensing far-field signals from the ventricles. To ensure consistency of the QuickOpt algorithm's performance, it is recommended that unipolar atrial sensing, which can be obtained from any unipolar or bipolar lead, be used whenever estimating the IACT.

In conclusions, P wave durations were similar between unipolar and bipolar atrial IEGMs in patients with standard pacemakers and CRT-D devices when the TRS of the leads are 10 mm or greater. These measurements are reasonably close to the surface ECG P wave duration, indicating that bipolar and unipolar AEGMs can be used as an effective surrogate for the surface ECG in estimating IACT. Unipolar AEGMs are preferred for estimating IACT over bipolar AEGM as the unipolar configuration will be independent of leads with different inter-electrode spacing.

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