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Automated detection of effective left-ventricular pacing: going beyond percentage pacing counters

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Aims Cardiac resynchronization therapy (CRT) devices report percentage pacing as a diagnostic but cannot determine the effectiveness of each paced beat in capturing left-ventricular (LV) myocardium. Reasons for ineffective LV pacing include improper timing (i.e. pseudofusion) or inadequate pacing output. Device-based determination of effective LV pacing may facilitate optimization of CRT response.

Methods and results Effective capture at the LV cathode results in a negative deflection (QS or QS-r morphology) on a unipolar electrogram (EGM). Morphological features of LV cathode−RV coil EGMs were analysed to develop a device-based automatic algorithm, which classified each paced beat as effective or ineffective LV pacing. The algorithm was validated using acute data from 28 CRT-defibrillator patients. Effective LV pacing and pseudofusion was simulated by pacing at various AV delays. Loss of LV capture was simulated by RV-only pacing. The algorithm always classified LV or biventricular (BV) pacing with AV delays $\leq$60% of patient's intrinsic AV delay as effective pacing. As AV delays increased, the percentage of beats classified as effective LV pacing decreased. Algorithm results were compared against a classification truth based on correlation coefficients between paced QRS complexes and intrinsic rhythm QRS templates from three surface ECG leads. An average correlation $>$0.9 defined a classification truth of ineffective pacing. Compared against the classification truth, the algorithm correctly classified 98.2% (3240/3300) effective LV pacing beats, 75.8% (561/740) of pseudofusion beats, and 100% (540/540) of beats with loss of LV capture.

Conclusion A device-based algorithm for beat-by-beat monitoring of effective LV pacing is feasible.

Keywords Cardiac resynchronization therapy • Percent pacing • Effective LV pacing • Electrograms

Introduction

Cardiac resynchronization therapy (CRT) is currently indicated in patients with heart failure, reduced left-ventricular ejection fraction (LVEF $\leq$ 35%), and a QRS duration $\geq$120 ms.[1] A fundamental requirement of CRT is the need to ensure delivery of a high percentage of ventricular pacing.[2] Several studies have shown that even small reductions in pacing percentage can adversely impact patient outcomes.[2–5]

Another fundamental requirement of CRT is capture of a significant portion of LV myocardium during LV pacing.[1,6] Devices report percentage pacing counters; however, a high percentage of ventricular pacing alone does not confirm effective LV pacing. Two common causes for ineffective LV pacing are loss of LV capture and the presence of pseudofusion. The latter can result when the atrioventricular (AV) interval is programmed too long or when effective pacing is inhibited by intrinsic AV conduction [e.g. during periods of atrial fibrillation (AF)].

Currently, the surface ECG is the only available means for confirming effective LV pacing.[7,8] One study of 24-h ECG recordings found an association between prevalence of pseudofusion and non-response to CRT in permanent AF patients.[9] A device-based diagnostic that reported effective LV pacing would enhance the utility of percentage pacing counters and could help optimize response to CRT. The aim of this study was to assess the feasibility of such a device-based diagnostic for the assessment of effective LV pacing.

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What's new?

- Current CRT-D devices report percent pacing but not the effectiveness of each LV paced beat.
- Effective LV pacing from the LV pacing cathode can be determined from the morphology of the unipolar LV electrogram.
- A device-based algorithm to classify each paced beat as effective or ineffective has high accuracy.
- Device-based determination of effective LV pacing may facilitate improved CRT response.

Methods

Development of algorithm

An automated algorithm was developed to confirm effective LV pacing from the pacing cathode. The algorithm was based on a fundamental principle in electrophysiology—effective capture of tissue generates a QS or QS-r morphology on the unipolar electrogram measured from the pacing cathode to an indifferent electrode.[10] The pacing cathode is any pacing pole of any commercially available unipolar, bipolar, or quadripolar LV lead; the indifferent electrode is the RV coil of the ICD lead. The resulting EGM was analysed within a predefined time-window (170 ms) starting from the instant at which pacing was delivered. The 170 ms incorporates the morphological signature of the depolarization complex without including features of repolarization (e.g. T-wave), which may interfere with the algorithm. *Figure 1A* compares typical EGM signals during effective pacing, ineffective pacing due to loss of LV capture, and ineffective pacing due to pseudofusion. Because the LV cathode is used both for pacing and for EGM amplification, a period of blanking follows the delivery of pacing. This blanking creates an artefactual flat portion of the EGM, where the pre-paced value of the EGM is held constant. The dotted horizontal line in each panel shows the isoelectric (zero-voltage) line. Following an effective pace, the EGM immediately after blanking has a negative deflection with a QS or QS-r morphology (*Figure 1A*-i). During ineffective pacing due to loss of LV capture (*Figure 1A*-ii) or pseudofusion (*Figure 1A*-iii), the EGM immediately after blanking has a positive deflection (R-wave). In instances where pseudofusion is present (LV pacing delivered after local tissue has already activated), the post-pace blanking hides a substantial portion of the evoked response (*Figure 1A*-iii). Thus, some portion of the R-wave (dotted portion of the EGM in *Figure 1A*-iii) before and after pacing is missing from the EGM signal within the analysis window. The elevated value of the flat portion of the EGM (during blanking) is therefore a hallmark of pseudofusion.

Based on the afore-mentioned observations, the following morphological features of the LV cathode–RV coil EGM were considered for development of an effective LV pacing algorithm (*Figure 1B*):

(1) Baseline amplitude (BL), which is defined as the EGM amplitude at the time pacing was delivered.
(2) Minimum amplitude (Min) and timing of the minimum amplitude (T_{min}) measured from the time at which pace is delivered.
(3) Maximum amplitude (Max) and timing of the maximum amplitude (T_{max}) measured from the time at which pace is delivered.

Based on a development data set of LV tip–RV coil EGMs and surface ECGs from 10 patients with a CRT-D device (*Table 1*), the following criteria for effective LV pacing were established: T_{min} must occur at least 23 ms before T_{max} and the ratio of magnitudes of Max minus BL and BL

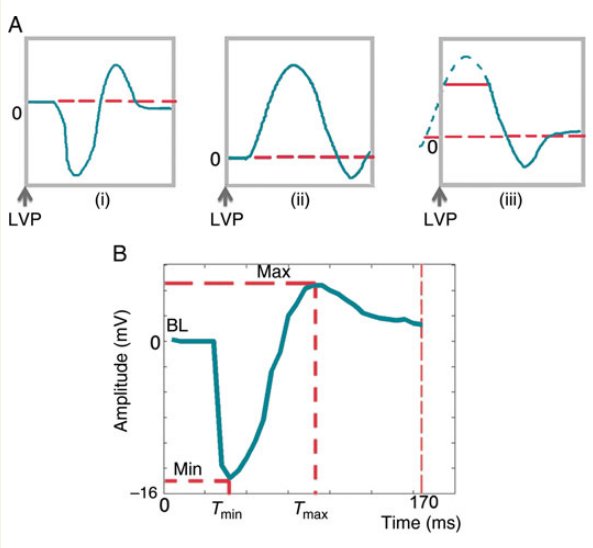

Figure 1 (*A*) Conceptual diagrams of LV cathode–RV coil EGMs following left-ventricular (LV) pacing that are characteristic of (i) effective LV pacing, (ii) ineffective LV pacing from loss of capture, and (iii) ineffective LV pacing from pseudofusion. The dotted horizontal line shows the isoelectric (zero-voltage) line for each plot. The horizontal portion of the solid line results from post-pace blanking of the EGM, which can conceal the actual EGM (dashed line in iii). (*B*) Morphological features considered in the development of an effective biventricular pacing algorithm, baseline amplitude (BL), maximum amplitude (Max), and time to maximal amplitude (T_{max}), minimum amplitude (Min), and time to minimal amplitude (T_{min}). These parameters were calculated from the unipolar electrogram signal within a 170 ms window starting from the time at which pacing was delivered. EGM, electrogram; LVP, LV pacing.

Table 1 Characteristics of the development and validation cohorts

Data set	Development	Validation
Patients, *n*	10	28
Age, years	70 ± 7	68 ± 7
Sex, male, *n* (%)	7 (70)	19 (68)
QRS duration, ms	162 ± 26	154 ± 23
QRS morphology, *n* (%)		
LBBB	9 (90)	20 (71)
IVCD	1 (10)	08 (29)
Left-ventricular ejection fraction, %	28 ± 6	26 ± 6
Aetiology of cardiomyopathy, *n* (%)		
Ischaemic	4 (40)	14 (50)
Non-ischaemic	6 (60)	14 (50)
LV pacing vector, *n* (%)		
LV tip-LV ring	5(50)	14 (50)
LV tip–RV Coil	5(50)	14 (50)

LBBB, left bundle branch block; IVCD, intraventricular conduction delay.

minus Min must be between 0.125 and 8. Any beat that does not meet these effective pacing criteria receives an ineffective classification.

Validation data set

Twenty-eight patients implanted with a Medtronic CRT-defibrillator were used to validate the effective LV pacing algorithm (*Table 1*). These patients had similar clinical characteristics to the 10 patients used for algorithm development. All patients provided informed consent, the study protocol was approved by local Ethics Committee, and the study complies with the Declaration of Helsinki. The validation data set was completely separate from the development data set, although the same data collection protocol was used for both data sets. All patients were in sinus rhythm and had LV capture management (LVCM) programmed on. The LV pacing vector was either LV tip-LV ring ($n = 14$) or LV tip–RV coil ($n = 14$); the RV pacing vector was RV tip-RV ring. Device data, including atrial and ventricular event markers and the LV tip–RV coil EGM were collected using custom telemetry Holters (DR-220, Northeast Monitoring, Maynard, MA). The EGM range was set to ± 16 mV to minimize clipping. LV pacing was delivered at least 2.0 V above the latest daily capture threshold as determined by LVCM to provide adequate pacing output to ensure LV capture. Biventricular (BV) and LV only pacing was performed in each patient starting with a short-sensed AV delay of 80 ms; the AV interval was incremented during pacing in 20 ms steps until ventricular sensing occurred. In addition, RV-only pacing (to simulate loss of LV capture) was delivered at an AV delay of 100 and 140 ms (the latter in patients whose intrinsic AV delay was >140 ms). Finally, a segment of intrinsic rhythm (inhibiting pacing by performing an underlying rhythm test) was collected. Three precordial ECG leads (V1, V3, V6) were also collected (Heartscape Technologies, Verathon, Seattle, WA) to document changes in the ECG morphology in the horizontal plane and to provide ineffective/effective LV pacing classification truth during BV/LV pacing (by correlating paced morphologies to intrinsic morphologies). The EGM data collected by DR220 Holters were digitized at 180 Hz, while the ECG data were sampled at 1 kHz. All pacing was performed in DDD mode. During pacing, any sensed beats due to ventricular ectopy were excluded. At least 10 beats were collected at each AV setting for RV-only pacing (LOC), LV-only pacing, and BV pacing.

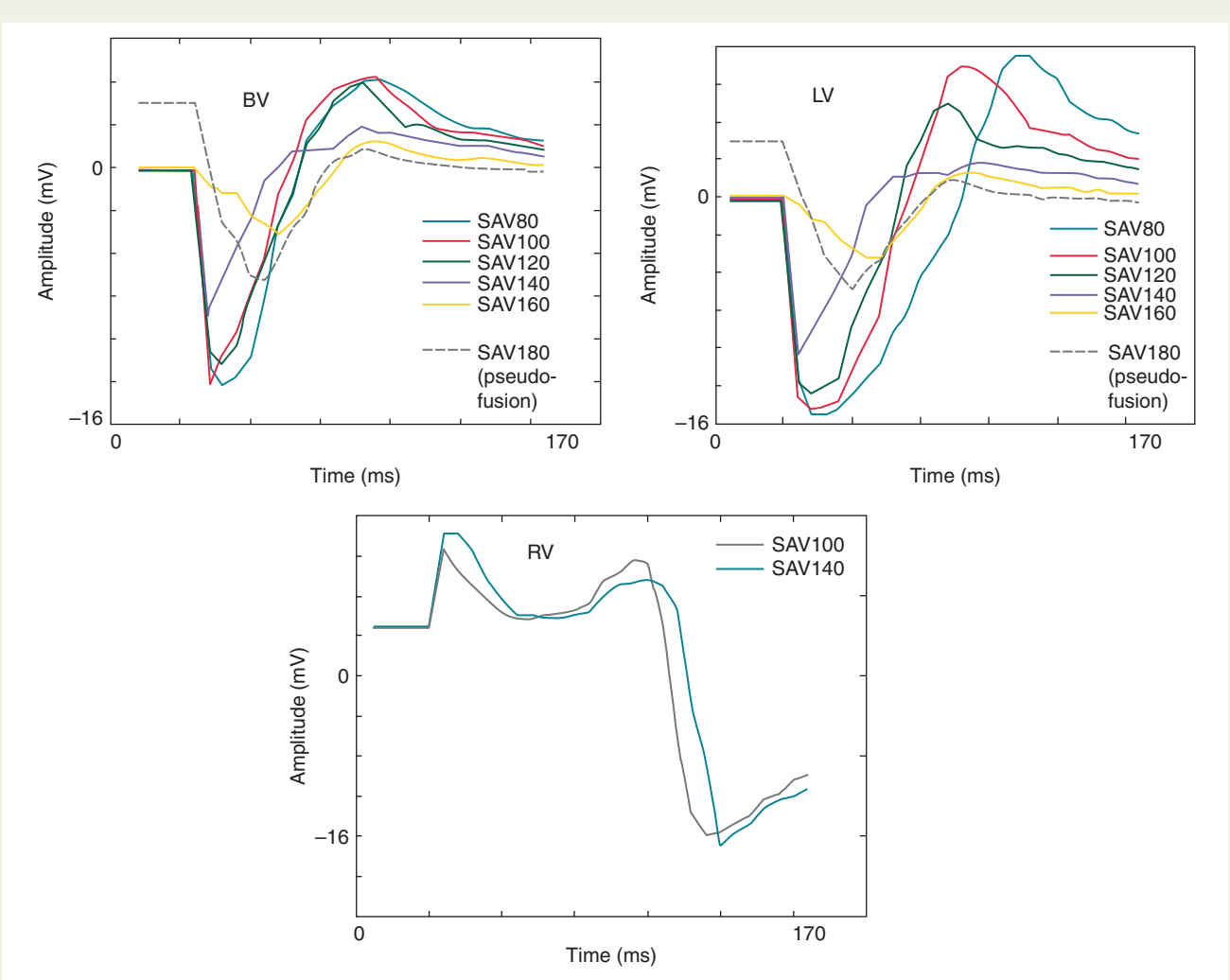

Figure 2 LV tip–RV coil EGM morphologies during BV pacing (top, left), LV-only pacing (top, right), and RV-only pacing (bottom) at varying programmed AV intervals. The patient's intrinsic AV delay was 190 ms. All EGMs during BV and LV pacing had QS/QS-r morphologies except for the ones corresponding to the longest AV delay of 180 ms. The EGMs during RV-only pacing had broad R-waves.

Definitions of ECG-based classification

Each beat was assigned an ECG-based classification truth (effective or ineffective LV pacing) for comparison to EGM-based algorithm classifications, according to the following definitions. Beats with RV-only pacing (simulating loss of LV capture) were always defined as ineffective LV pacing. Definition of effective vs. ineffective LV pacing during BV/LV pacing was based on the correlation between paced and intrinsic QRS morphologies in the surface ECG. Specifically, the Pearson correlation coefficient was determined between the QRS complexes of the candidate paced beats and those of intrinsic depolarization, for each of the three precordial leads V1, V3, and V6. A 220 ms time-window was chosen for generating QRS templates, starting from onset of QRS. The 220 ms window was chosen because it allows incorporation of the entire intrinsic QRS complex which is necessary for correct computation of correlation coefficient. For each beat, if the average correlation coefficient between paced and intrinsic templates for the three leads exceeded 0.9, the beat was defined as ineffective pacing; else the beat was defined as effective pacing. The threshold of 0.9 was chosen arbitrarily as correlation coefficients above 0.9 typically reflect a high degree of similarity. In total, the data set included 3300 beats with effective LV pacing, 740 beats with pseudofusion, and 540 beats with loss of LV capture (RV only pacing) according to the ECG correlation-based classification truth.

Results

Examples of LV tip–RV coil EGMs collected at different AV delays during BV/LV/RV pacing in a representative patient are shown in *Figure 2*. During both BV and LV-only pacing, short AV delays result in negative deflection (QS or QS-r morphology) followed by a small positive deflection. However, at an AV interval of 180 ms, the EGM has an elevated baseline (>0 mV), with T_{max} occurring *before* T_{min}, where T_{max} and T_{min} are defined in *Figure 1B* (note that baseline can also be the maximum amplitude, as occurs for the 180 ms AV interval). In contrast, during RV-only pacing (simulating loss of LV

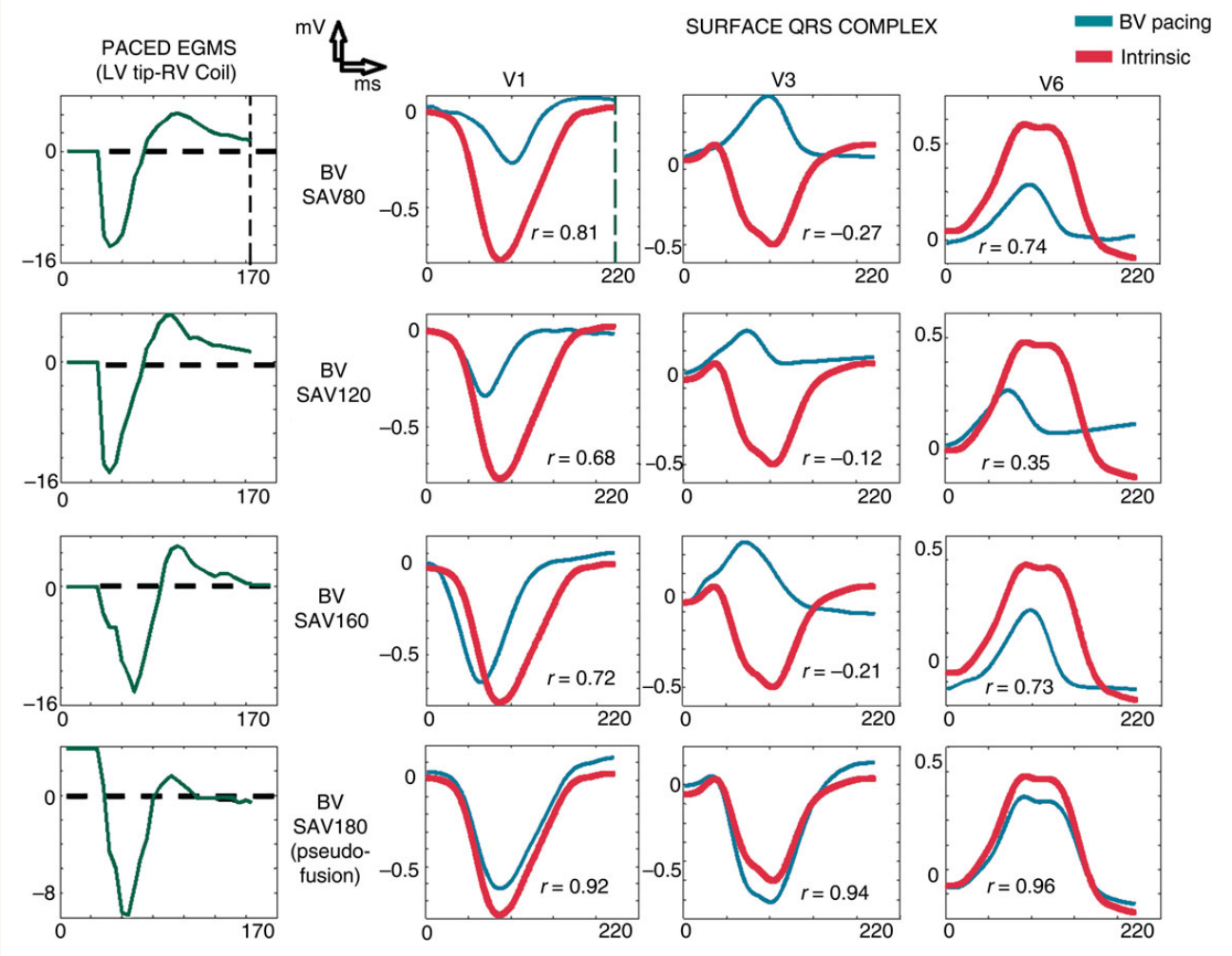

Figure 3 LV tip–RV coil EGM (left) and surface QRS complexes (right) during BV pacing vs. intrinsic rhythm at varying programmed AV intervals. Three precordial leads, V1, V3, and V6 are shown. Each panel on the right overlays the BV-paced QRS complex (blue) along with the intrinsic QRS template (red), and shows the correlation coefficient (*r*) between the paced and the intrinsic complexes. The correlation coefficient between intrinsic and paced QRS complex at the longest AV delay (180 ms), was >0.9 for each of the three leads. The X-axis is in milliseconds and Y-axis is in milliVolts.

capture), the LV EGM is characterized by a broad R wave that is *always* >0 mV; the T_{max} again occurs before T_{min}.

Examples of LV tip–RV coil EGMs and corresponding precordial ECGs are shown in *Figure 3* (for BV pacing) and in *Figure 4* (for LV-only pacing, in the same patient). These figures also show the correlation coefficients of each paced ECG to the intrinsic ECG at different sensed AV delays. When effective pacing occurs (i.e. with correlation coefficient between paced and intrinsic surface ECG < 0.9), the EGMs are broadly characterized by a negative deflection (QS or QS-r morphology), followed by a small positive deflection. In contrast, pacing at longer AV delays results in correlation coefficients between paced and intrinsic surface ECG > 0.9, and the EGM morphology starts with a large positive deflection (i.e. starts above the isoelectric line).

When the device-programmed AV interval was <60% of the patients' intrinsic AV intervals, the LV unipolar EGM algorithm always classified the beats as effective LV pacing (*Figure 5*). However, as the programmed AV delay increased, the percentage of beats classified as effective pacing decreased. When the programmed AV interval was >90% of the patient's intrinsic AV interval, all paced beats were classified as ineffective.

The algorithm provided an effective classification for 3240 (98.2%) of 3300 beats defined as effective (by surface ECG correlation criteria). The algorithm classified 540 (100%) of 540 confirmed ineffective paced beats (due to loss of LV capture) as being ineffective. Finally, the algorithm classified 561 (75.8%) of 740 pseudofusion beats (defined by the surface ECG correlation criteria), as being ineffective.

Since the definitions of effective vs. ineffective LV capture were based on a single threshold of correlation coefficient between paced and intrinsic ECG complexes, the performance of the algorithm was studied with definitions of effective and ineffective LV capture based on different thresholds of correlation coefficients ranging from 0.80 to 0.95. There was no major change in the performance of the algorithm for thresholds of correlation coefficient around

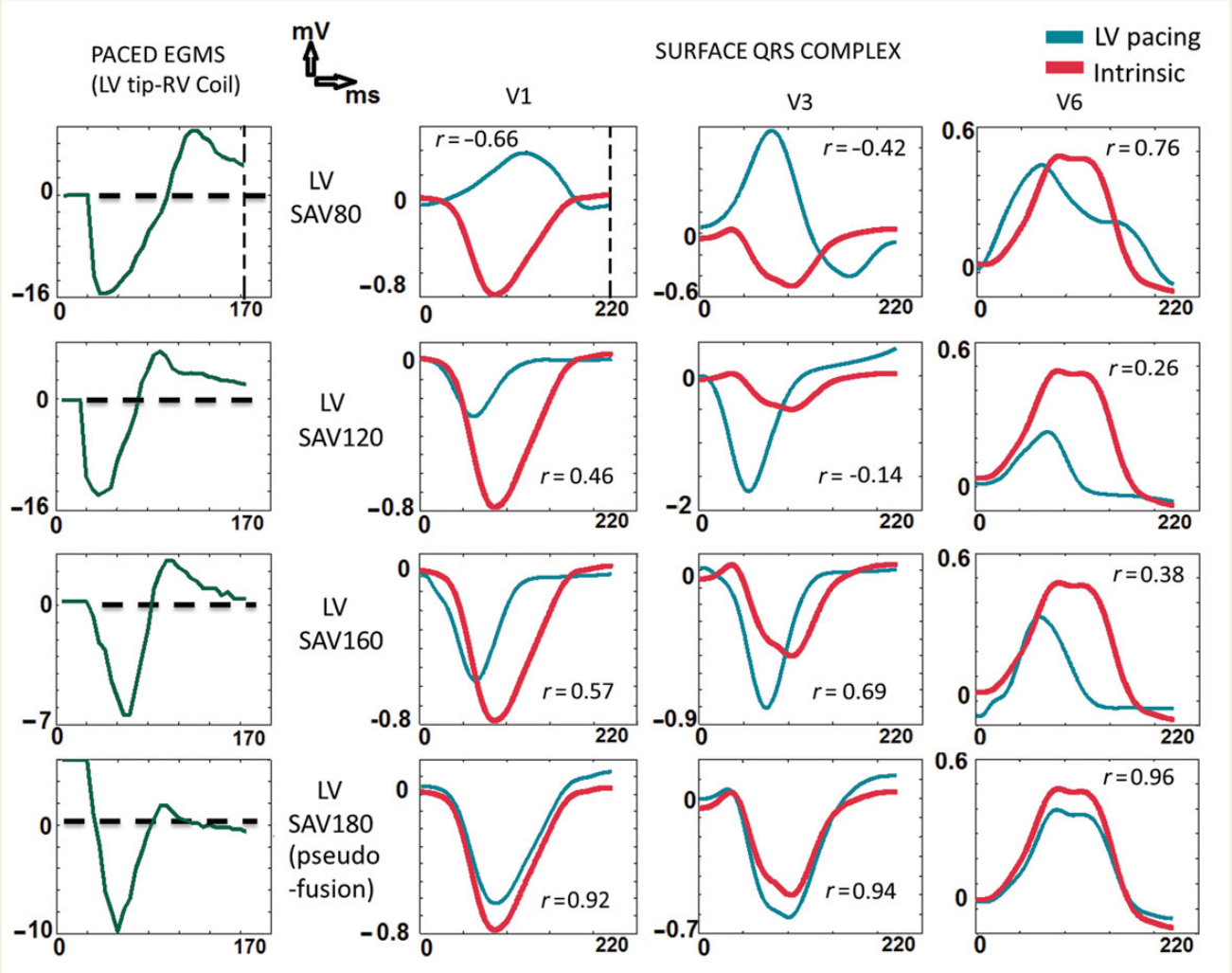

Figure 4 LV tip–RV coil EGM (left) and surface QRS complexes (right) during LV pacing vs. intrinsic rhythm at varying programmed AV intervals. Three precordial leads, V1, V3, and V6 are shown. Each panel on the right overlays the LV only paced QRS complex (blue) along with the intrinsic QRS template (red) and shows the correlation coefficient (*r*) between the paced and the intrinsic complexes. The paced surface complexes at the longest AV interval (180 ms) were similar to intrinsic. The X-axis is in milliseconds and Y-axis is in milliVolts.

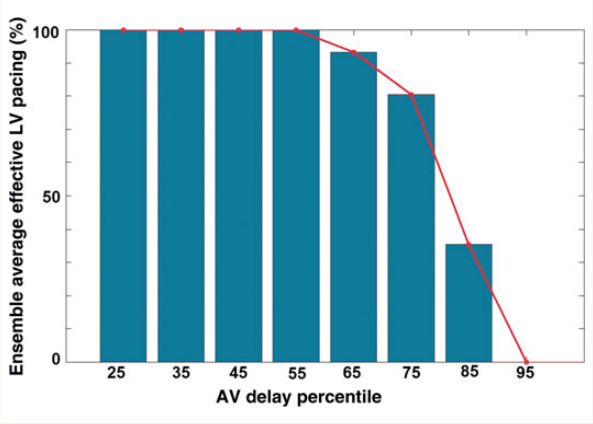

Figure 5 Effective percentage of LV pacing as a function of programmed AV interval for all patients ($n = 28$). For programmed AV delays up to 60th percentile of intrinsic, the algorithm classified all beats as effective pacing. For AV delays >90th percentile, all beats were classified as ineffective pacing.

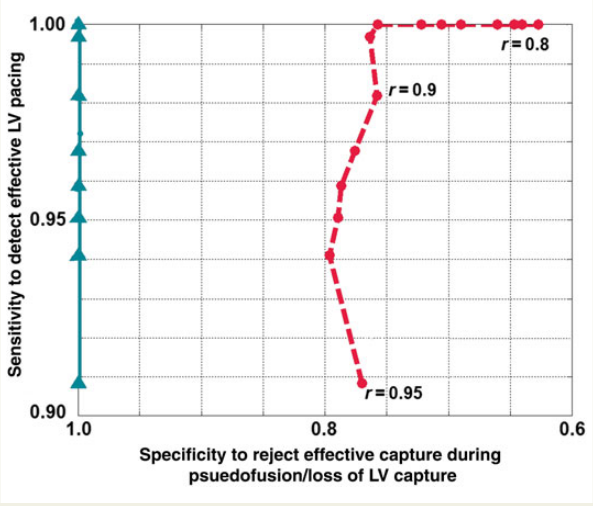

Figure 6 Comparison of performance (sensitivity/specificity) of the effective LV pacing algorithm for different thresholds of average correlation coefficient between paced QRS and intrinsic QRS (used for discriminating ineffective from effective LV pacing) at three precordial leads V1, V3, and V6. The curve on the right (circles) shows the sensitivity/specificity values for effective pacing vs. pseudofusion, the curve on the left (triangles) shows the corresponding values for effective pacing vs. loss of capture. The different correlation thresholds used for detecting pseudofusion from surface ECG are also shown in the figure.

0.9, as shown in *Figure 6*. *Table 2* summarizes the sensitivity and specificity of the algorithm for identifying effective vs. ineffective pacing (pseudofusion) for different thresholds of correlation coefficients.

Table 2 Sensitivity and specificity for the effective capture algorithm for discriminating between effective capture and pseudo-fusion

Threshold for correlation with intrinsic ECG	Sensitivity %	Specificity %
0.8	100	62.72
0.81	100	64.02
0.82	100	64.68
0.83	100	66.06
0.84	100	69
0.85	100	70.56
0.86	100	72.20
0.87	100	75.73
0.88	100	75.73
0.89	99.69	76.37
0.9	98.18	75.81
0.91	96.77	77.57
0.92	95.88	78.68
0.93	95.07	78.94
0.94	94.11	79.61
0.95	90.84	77.02

Discussion

The principal finding of this study is that automated device-based monitoring for effective LV pacing is feasible with 100% of beats with loss of LV capture classified as ineffective, 98.2% of effective LV-pacing beats classified as effective, and 75.8% of pseudofusion beats classified as ineffective LV pacing. The algorithm misclassified 1.8% of the effective LV-paced beats as ineffective LV pacing. However, the surface ECG correlation between paced and intrinsic QRS for these misclassified beats were all between 0.88 and 0.90, just under the threshold used for defining ineffective LV pacing. In addition, all of these beats had AV delays ≥80% of the intrinsic AV delay, suggesting a high probability of pseudofusion.

In contrast, about 25% of pseudofusion beats were misclassified by the algorithm as effective LV pacing. The LV unipolar EGM associated with these beats had a negative initial deflection. It is possible that some degree of LV tissue capture still occurred in these cases as reflected by the QS morphology of the LV EGM. It is important to note that correlation with surface ECG was used to define effective vs. ineffective LV pacing, and a small degree of local LV tissue capture may not be reflected on the surface ECG. Direct activation mapping of the ventricles is probably necessary to establish a true gold standard classification. However, for obvious reasons, this was not practical in this study.

When used as a CRT device diagnostic, it is important for such a metric to have nearly 100% sensitivity for detection of effective LV pacing. A very high sensitivity reduces the possibility of false alarms and the associated burden of device check and follow-up. Our EGM-based algorithm had 98.2% sensitivity. On the other hand, the algorithm identified ineffective LV pacing in majority of the cases (100% for loss of LV capture and 75% for pseudofusion). Existing algorithms for the determination of effective capture are based on the 12-lead ECG, which does not allow chronic monitoring.[7,8] Since the current algorithm is based on the device EGM and uses simple criteria for checking effective LV pacing, continuous monitoring by an implanted device is feasible.

A previous study validated algorithms for verifying LV capture during biventricular pacing using evoked response morphology.[11] However, that algorithm, as well as other LVCM algorithms,[12] are validated at very short AV delays and are not able to operate during fusion. Our algorithm can classify effective capture in the presence of fusion. This is important because CRT is usually delivered at AV delays where some degree of fusion occurs in patients with intrinsic AV conduction.

Clinical importance

The routine incorporation of this algorithm into clinical practice offers several important opportunities to improve patient outcomes. We observed that effective pacing can be ensured with pacing at short AV intervals; however, it has been shown that the optimal AV delay during CRT targets maximum filling time. At these longer AV intervals, the surface ECG shows fusion and it can be difficult to define the optimal AV delay.[13] The present algorithm may help identify the longest AV delay that still permits effective LV pacing.

Periodic or continuous monitoring of effective LV pacing is important in sinus rhythm patients. If there is ineffective pacing during sinus rhythm, shorter AV delays, a change in V–V delay towards earlier LV activation, or an increase in pacing output may be necessary to ensure more consistent effective capture.

Another value of the algorithm may be in patients with AF, which is common and remains challenging to manage in CRT patients.[14–16] Previous studies have shown that there is benefit of CRT in AF patients; however, maximizing CRT in these patients is necessary to ensure clinical benefit.[9] In this patient population, pseudofusion (due to intrinsic AV conduction) corrupts the pacing counters leading to an overly optimistic view of effective pacing.[1,9] The present algorithm could estimate the proportion of pacing that is actually resulting in effective pacing during AF. This in turn could enhance clinical decisions regarding optimization of medical therapy and/or decisions to perform catheter ablation (e.g. AV junction ablation).

Finally, in both sinus rhythm and AF patients, this algorithm can help identify loss of LV capture at the programmed LV cathode, allowing for an opportunity to adjust pacing vectors and/or output accordingly. To maximize longevity and avoid phrenic nerve stimulation, small LV capture safety margins are often chosen. However, it is not known how successful this strategy is for maintaining chronic effective LV pacing. This feedback could be important for evaluating the tradeoff between higher safety margin and longevity/phrenic stimulation avoidance, and may help improve CRT response by ensuring that a high degree of effective LV pacing is delivered at the programmed margins.

Limitations

This study has several limitations. First, all data in this study were acquired with the patient at rest and in a supine position. Postural changes may impact the LV EGM amplitudes; however, the gross morphology of EGMs is not expected to change.[17] Future studies will require analysis of LV EGM morphologies acquired from 24-h Holters to assess the impact of exercise on the results. Secondly, all patients underwent BV pacing with no interventricular offset. Thirdly, all patients in the study had a CRT-D device. However, the same concept can apply to CRT-P devices where the EGM vector of interest would be LV cathode – Can. The study did not include any AF patients, though in principle, the concept and the algorithm described here could be applied for detection of pseudofusion beats during AF. Lastly, there were no right bundle branch block (RBBB) patients in the cohort and the impact of LV lead location on the performance of the algorithm was not assessed. However, since the fundamental principle of detection of effective pacing is based on QS or QS-r morphology on the unipolar electrogram, the algorithm should be applicable in all patients independent of intrinsic conduction disorder or LV lead location.

Conclusions

An automated CRT device algorithm based on analysis of gross morphological features of unipolar LV EGM was developed for detection of effective LV pacing and validated using an independent data set. The algorithm had near 100% sensitivity in determination of effective pacing. The proportion of effective LV pacing based on such an algorithm would be a valuable addition to the current CRT device diagnostics.

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Conflict of interest: S.G. and R.W.S. are Medtronic employees; S.M. is a consultant to Biotronik, Boston Scientific, Medtronic, Sorin, and St Jude Medical.

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Coronary vein pacing with standard active fixation leads for cardiac resynchronization

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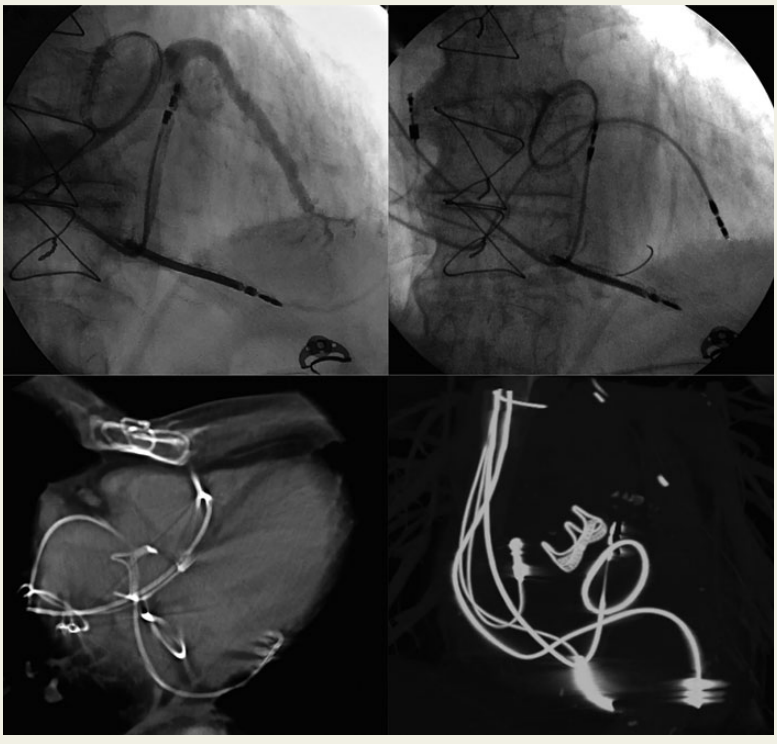

Left ventricle (LV) pacing lead position is often hampered by lead instability and dislodgment. Specific active fixation leads have been designed, yet their popularity has waned due to technical difficulties upon extraction. Standard active fixation lead implantation in the coronary sinus has been safely used in the past for atrial pacing. We report three cases in which standard screw-in active fixation leads were implanted in the venous circulation for LV pacing. All patients have a dilated cardiomyopathy with severely depressed systolic function and symptomatic heart failure (NYHA class III). Patient 1 had had a CRT-D previously, with an active fixation LV lead (Medtronic Attain Starfix) due to standard lead instability. Full explantation was required 1 year later due to infection. Given that LV lead extraction was extremely challenging, a standard active fixation lead (Medtronic Capsure Fix Novus) was successfully implanted in a left postero-lateral vein (*Figure*). Three-year follow-up has demonstrated stable pacing thresholds (<1.5 V at 0.4 ms) without complications (namely pericardial effusion). Patients 2 and 3 were implanted similarly on first implant given our previous experience with Patient 1, with follow-up showing similar thresholds and no complications.

The full-length version of this report can be viewed at: http://www.escardio.org/Guidelines-&-Education/E%E2%80%93learning/Clinical-cases/Electrophysiology/EP-Case-Reports.