Fluctuation of left ventricular thresholds and required safety margin for left ventricular pacing with cardiac resynchronization therapy

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Aims
Fluctuations in left ventricular (LV) thresholds with cardiac resynchronization therapy (CRT) are unknown. The LV capture management (LVCM) algorithm automatically measures LV thresholds on a daily basis and offers the opportunity to analyse threshold fluctuations.

Methods and results
A total of 282 patients implanted with a Medtronic Concerto CRT-D device were prospectively studied. Device data were collected at periodic visits, including daily thresholds from the preceding 14 days and weekly threshold ranges since implantation, acquired by the LVCM algorithm up to 12 months’ follow-up. Overall, LV thresholds remained relatively stable, with 189/208 (91%) patients having a maximum increase in threshold of ≤1.0 V at any time between their 1 and 6 month visits and 127/135 (94%) between the 6 and 12 month visits. However, increase in threshold was significantly affected by LV threshold amplitude. Of the 170 patients with a 1 month threshold of ≤2.0 V, 159 (94%) had increases of ≤1.0 V up to their 6 month visit, whereas 8/38 (21%) patients with >2.0 V threshold had increases of >1.0 V (P = 0.01). There were no significant changes in LV threshold amplitude and fluctuation over the 12 month follow-up.

Conclusion
For patients with low (≤2.0 V) LV thresholds, a safety margin of 1.0 V is sufficient to ensure LV capture if phrenic nerve stimulation is an issue, and may be even lower in devices with auto-adaptive capture management algorithms. However, the margin should be greater in patients with higher thresholds because of larger fluctuations. Left ventricular capture management may be particularly useful in these patients to ensure LV capture without sacrificing device longevity.

Keywords Cardiac resynchronization therapy • Pacing • Threshold • Left ventricular capture management

Introduction
The prerequisite for successful cardiac resynchronization therapy (CRT) is left ventricular (LV) capture. It has previously been shown that up to 36% of patients had loss of CRT delivery at some point in time over follow-up. One of the reasons for loss of CRT delivery is loss of LV capture that may be observed in 10% of patients.1 Left ventricular thresholds are known to be higher than for right ventricular leads.2–4 Left ventricular leads implanted via coronary sinus tributaries may have less stable tip contact than right ventricular endocardial leads, which results in greater threshold fluctuations. There is no consensus as to what safety margin should be programmed for LV pacing. This becomes an issue in cases of high thresholds (as pacing output affects device longevity) as well as with phrenic nerve stimulation (encountered in up to 18% of patients5).

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The advent of the Medtronic (Minneapolis, MN, USA) left ventricular capture management (LVCM) algorithm that automatically measures LV thresholds on a daily basis, offers us the opportunity to analyse threshold fluctuations. Our aims were to assess the required safety margin for LV capture with CRT, and factors affecting LV-threshold fluctuations.

**Methods**

**Patient population**
A total of 282 patients enrolled in the Concerto® AT Clinical Study were included. The study was a prospective, multicentre, non-randomized clinical trial designed to assess the safety and efficacy of the Concerto® system. All patients had a standard indication for CRT and an ICD (NYHA class III/IV under optimal medical therapy, QRS ≥120 ms, LV ejection fraction <35%6–8). Patient demographics are shown in Table 1. All patients provided informed consent to the study, which was approved by the institutional ethics committee.

**Left ventricular capture management (LVCM) algorithm**

The Medtronic Concerto CRT-ICD features the LVCM algorithm, which automatically measures LV thresholds as previously described in detail.9 Basically, capture detection is performed by pacing the LV lead and assessing the timing of the ventricular sense on the right ventricular lead. Since the interventricular interval tends to be shorter than the atrioventricular (AV) interval, a captured test pace will be sensed in the opposite chamber earlier than the AV conducted ventricular sense on a non-captured test pace. After evaluating ventricular rate (R–R variability <200 ms and heart rate <90 bpm), the algorithm evaluates interventricular conduction (LVP–RVS) interval of 60–270 ms and variability of <30 ms), and ascertains that atrioventricular conduction is sufficiently longer than the interventricular time. An LV capture detection window is initiated within −30 and +20 ms of the maximum LVP–RVS interval. Loss of capture is defined as an RVS event that occurs >50 ms after the maximal LVP–RVS interval (that is assumed to be due to AV conduction). In patients without AV conduction or in patients with atrial fibrillation (AF) with a well-controlled ventricular rate, the interventricular conduction time may be used to assess capture. Thresholds are measured at the programmed pulse-width in 0.5 V steps between 0.5 and 3.5 V, and 1 V steps between 4.0 and 6.0 V (with three support cycles and one test cycle). After a loss of capture is detected, amplitude is incremented until capture is confirmed on three consecutive tests. As thresholds are performed in 0.5–1 V steps, it has to be borne in mind that a change in threshold from one day to another is approximated to ±0.4 V. Thus, a reported increase in threshold of 0.5 V (e.g. measured as 1.0 and 1.5 V on separate days) could in reality mean changes of 0.1–0.9 V i.e. either from 1.0 to 1.1 V (Δ = 0.1 V), or from 0.6 to 1.5 V (Δ = 0.9 V). The LVCM tests are scheduled on a daily basis at 01:00 am. If the test fails, a new test is programmed after 30 min, for up to four times. The algorithm has recently been shown to perform accurately, with 99.7% of in-office LVCM thresholds being within one step of the manual threshold.9

**Data collection and analysis**

Patients were followed-up at 1, 3, 6, and 12 months (with a mean follow-up of 10 ± 3 months). Data were retrieved from save-to-disk sessions. There were two LVCM datasets: daily LVCM thresholds over the 14 days preceding device interrogation, and weekly threshold maximum and minimum values over the last 80 weeks since implantation. Examples of LVCM measurements in individual patients are shown in Figure 1.

**Table 1** Study population demographics (percentages are rounded off)

| Patient demographics (n = 282) |  |
|-------------------------------|--|
| Mean age (years) | 66.9 ± 11.5 |
| Gender |  |
| Male | 201 (71%) |
| Female | 81 (29%) |
| Cardiomyopathy |  |
| Ischaemic | 158 (56%) |
| Non-ischaemic | 124 (44%) |
| NYHA class |  |
| III | 261 (93%) |
| IV | 21 (7%) |
| Hypertension | 181 (64%) |
| Diabetes | 105 (37%) |
| Atrial fibrillation |  |
| Paroxysmal | 81 (29%) |
| Persistent | 15 (5%) |
| Permanent | 0 (0%) |
| Indication |  |
| Primary prevention | 243 (86%) |
| Secondary prevention | 39 (14%) |
| Treatment |  |
| ACEI/ARB | 244 (87%) |
| Beta-blocker | 248 (88%) |
| Digitalis | 108 (38%) |
| Diuretic | 241 (85%) |
| Class III antiarrhythmic | 67 (24%) |
| Implanted LV lead model |  |
| 4194 | 168 (60%) |
| 4193 | 88 (31%) |
| Other | 26 (9%) |
| LV lead position |  |
| Lateral | 97 (34%) |
| Postero-lateral | 108 (38%) |
| Posterior | 18 (6%) |
| Antero-lateral | 32 (11%) |
| Anterior | 5 (2%) |
| Other/missing data | 22 (8%) |

**Maximum increase in left ventricular thresholds between the 1 and 6 month visits**

For the purposes of this analysis, the last measured LVCM threshold from the 14 day dataset preceding the 1 month visit was recorded as a surrogate for the in-office manual threshold. The LVCM threshold was chosen rather than the manual threshold, as definition of threshold may have varied between study centres (i.e. loss of capture vs. last captured beat). Maximum thresholds between 1 and 6 month visits were obtained from the weekly range data and compared with the 1 month threshold to calculate the maximum increase at any timepoint during this interval. The same was done between the
6 and 12 month visits. We chose these visits for analysis as patients with CRT are often followed-up every 6 months.

**Day-to-day fluctuations in left ventricular threshold over two week periods**

Analysis was restricted to complete 14 day datasets preceding device interrogation (i.e. without any missing threshold measurements over the last 14 days) that were obtained at any timepoint during the 12 month follow-up. Mean LV capture thresholds during the 2 week periods were calculated for analysing effect on LV threshold fluctuation.

**Statistical analysis**

Day-to-day threshold fluctuation over the 2 week periods was analysed by the trimmed range (10th–90th percentiles i.e. the difference between the one-but-largest and the one-but-smallest threshold values). This analysis was chosen in preference of the more common measures of dispersion: standard deviation (SD) and interquartile range, to give additional weight to cases where two or more measurements differ from the rest. Comparison of parameters between strata (different timepoints in follow-up, lead model, and pacing configuration) was performed by an ANOVA-type test with GEE correction to take into account multiple measurements per patient. Fisher’s exact test was used for analysing categorical variables. The relationship between trimmed range and LV threshold was evaluated by a linear regression analysis with GEE correction. The relationship between increase in threshold and 1 month threshold was analysed by ordinary least-squares regression. Data are expressed as mean ± SD. A two-sided P-value of <0.05 was considered statistically significant. All analyses were performed using SAS version 9.1 (SAS Institute Inc., Cary, NC, USA).

Figure 1 Examples of LVCM data from device interrogations. (A) Patient with a low LV threshold (0.5 V at 0.4 ms) and low threshold fluctuation (0 V), seen with both the weekly range data (to the left of the solid vertical line), and over the last 14 days (right of the vertical line). (B) Patient with a high LV threshold amplitude (mean threshold 4.6 V at 1 ms) and threshold fluctuation (trimmed range of 1.5 V) calculated from the 14 day data.
Results

Weekly threshold range data at any timepoint since implantation were available in 262 patients. The remaining 20 (7%) patients had absence of LVCM data. Of these, three patients were lost to follow-up after hospital discharge, six patients had the LVCM algorithm disabled, three patients had LV pacing disabled, another three patients were programmed to a non-supporting mode (AAI in two patients and DDIR in two patients), and in five (2%) patients the LVCM algorithm was unable to measure a threshold. This was likely due to similar LV–RV and AV conduction times in four patients, and rapidly conducted persistent AF in one patient.

The LVCM algorithm was programmed to ‘adaptive’ 53% of the time (meaning that the pacing amplitude was automatically adjusted according to the LVCM threshold, with a pre-defined safety margin), and to ‘monitor’ 47% of the time (meaning that LVCM threshold data were collected without adapting pacing output).

Maximum increase in left ventricular threshold during the interval between visits

One to 6 month interval

Weekly range data at the 6 month visit and 14 daily LVCM data at 1 month were available in 208 patients. As can be appreciated from Figure 2, increase in threshold at any timepoint between 1 and 6 months was relatively low in the majority of patients, with 171 (82%) patients showing increases of ≤0.5 V, and 189 (91%) increases of ≤1.0 V. Thus, 19 (9%) patients had increases in LV threshold of >1.0 V, with values up to 4 V (in 2 patients).

The probability of having a >1.0 V increase in threshold during follow-up was significantly affected by LV threshold at 1 month ($P = 0.009$), as was the mean increase in threshold ($P = 0.002$, Figure 3). Of the 170 patients with an LV threshold of ≤2.0 V at 1 month, 159 (94%) never had an increase in threshold of more than 1.0 V. For the other 38 patients with an LV threshold of >2.0 V, 8 (21%) had increases in threshold of >1.0 V ($P = 0.010$).

Six to 12 month interval

Data at both 6 and 12 month visits were available in 135 patients. Results were very similar to those obtained between the 1 and 6 month follow-ups. A total of 119 (88%) of patients had a maximal threshold rise of ≤0.5 V at any timepoint between 6 and 12 months, and 127 (94%) with increases of ≤1.0 V. Thus, eight (6%) patients had increases in LV threshold of >1.0 V, with values up to 5 V (in one patient). There was also a significant correlation between the 6 month threshold and the maximum increase in threshold between 6 and 12 months ($P = 0.012$).

Day-to-day left ventricular threshold fluctuation over 2 week periods

A total of 8176 daily LVCM measurements were analysed from 584 complete 14 day datasets in 207 patients. Of the 584 datasets, 546 (93%) had fluctuations (measured by the trimmed range) of 0–0.5 V, and 38 (7%) fluctuations of ≥1.0 V. Of the 207 patients, 26 (13%) had one or more complete dataset with ≥1.0 V threshold fluctuation (and up to 3.0 V fluctuation).

For comparison with the complete 14 daily measurements datasets, a total of 9327 weekly range measurements were analysed in 262 patients. Weekly ranges of 0 and 0.5 V were observed in 56 and 36% of weeks, respectively (totalling 92% of weeks together), ranges of 1.0 V were observed in 5% of weeks, and of >1.0 V in the remaining 3% of weeks. Thus, results were almost identical with both analyses, indicating that outlier measurements of LVCM (that may have affected the weekly range data) were not an issue.
Factors affecting day-to-day left ventricular threshold fluctuation over the 2 week periods

Threshold amplitude
There was a significant increase in daily LV threshold fluctuation with increase in mean LV threshold over the 2 week period. The trimmed range increased by 0.27 V for each 1.0 V increase in threshold (95% confidence interval 0.19–0.35, \( P < 0.0001 \)). As the LVCM algorithm measures threshold in steps of 0.5 V for thresholds up to 4.0 V and in steps of 1.0 V thereafter, we explored a possible bias in increased threshold fluctuation with increased threshold amplitude by limiting the analysis to 563 datasets of 200 patients with LV threshold ≤4.0 V. The results remained highly significant (\( P < 0.0001 \) by linear regression). Examples illustrating these findings are shown in Figure 1.

Time from implantation
There were no significant differences in the 14 day threshold fluctuations or mean LV thresholds between the different follow-up visits (Figure 4).

Lead models
There were no significant differences in LV threshold or threshold fluctuation between the Medtronic Attain 4194 (\( n = 126 \)), the Medtronic Attain 4193 (\( n = 59 \)), and other LV lead models (\( n = 22 \)) (\( P = 0.56 \)).

Lead position
Due to the number of different categories with few observations, we compared the postero-lateral position with all other lead positions, and found no difference in mean LV threshold (\( P = 0.24 \)) or threshold fluctuation (\( P = 0.68 \)).

Pacing configuration
The ‘LV tip to RV coil’ configuration (which is the nominal setting) was programmed in 76% of the 2 week periods, the ‘LV tip to LV ring’ configuration of the bipolar 4194 lead was programmed in 21% of the periods and the ‘LV ring to RV coil’ (e.g. to avoid phrenic nerve stimulation) programmed in 3% of the periods. The vast majority (98% of patients) had no change of LV pacing configuration over follow-up. There were no differences in threshold data between the first two configurations. The ‘LV ring to RV coil’ configuration, however, showed significantly higher LV thresholds than with the other two configurations (2.53 ± 0.62 V vs. 1.44 ± 0.85 V and 1.62 ± 0.82 V, respectively, \( P = 0.001 \)) and a trend towards higher threshold fluctuations (0.44 ± 0.31 V vs. 0.28 ± 0.38 V and 0.29 ± 0.47 V, respectively, \( P = 0.11 \)). It should be borne in mind that the 4194 lead has an LV ring with a large surface (38 mm²), and this feature may increase thresholds when the ring is used as a cathode.

Pulse width
The majority (88% of patients) had the same pulse width programmed during the entire follow-up. A pulse width of 0.4 or 0.5 ms was programmed in 77% of complete datasets, and of ≥0.6 ms in 23%. There were no differences in LV threshold amplitude between these groups (1.44 ± 0.73 V vs. 1.75 ± 1.17 V, \( P = 0.22 \)). Likewise, there were no differences in LV threshold fluctuation (0.27 ± 0.37 V vs. 0.36 ± 0.50 V, \( P = 0.37 \)).

Baseline characteristics
There was no significant relation between LV threshold fluctuation and the following baseline characteristics: age (\( P = 0.81 \)), gender (\( P = 0.39 \)), NYHA class (\( P = 0.76 \)), LVEF (\( P = 0.42 \)), QRS width (\( P = 0.57 \)), heart failure aetiology (\( P = 0.20 \)), and the use of ACE inhibitors (\( P = 0.48 \)) or beta-blockers (\( P = 0.11 \)).

Discussion
The main finding of our study is that the majority of patients have stable LV thresholds over follow-up. Nevertheless, almost 1 in 10 patients has an increase of >1.0 V in LV threshold compared with the 1 month threshold at some timepoint during the following 5 months. Our analysis indicates that high LV threshold fluctuation is significantly related to higher LV pacing threshold amplitude. This is most probably due to suboptimal stability and contact with the epicardium of the LV electrode. Proximity to scar tissue may also play a role, but the fact that patients with ischaemic and non-ischaemic cardiomyopathy had similar threshold fluctuation, argues against this.

There are several clinical implications for devices without automated algorithms that adjust LV output according to threshold measurements. First, in case of a high (>2.0 V) LV pacing threshold, a sufficient safety margin should be programmed to ensure continuous LV capture. One in five of these patients has a >1.0 V increase in LV thresholds during the 1–6 month follow-up period. The conventional 100% safety margin (usually obtained by doubling the threshold amplitude) should be sufficient in most cases. However, a high LV pacing output may lead to premature battery depletion or to other complications such as
extracardiac (e.g. phrenic nerve) stimulation. The LVCM algorithm (set to the ‘adaptive’ mode) may be particularly useful in these patients to ensure LV capture, without sacrificing device longevity. Second, in case of phrenic nerve stimulation, a low threshold safety margin e.g. 1.0 V may be programmed, as long as the LV threshold is low (<2.0 V). The LVCM algorithm set to the ‘adaptive’ mode may again be useful in these cases (and will also serve to maximize device longevity). Analysis of day-to-day and weekly threshold fluctuation data in the device diagnostics is useful for determining the optimal safety margin for a given patient (the default value being 1.5 V), and may allow margins as low as 0.5 V in patients with stable day-to-day thresholds.

In the era of telemedicine, remote device follow-up is becoming increasingly popular. However, an in-office visit can only be replaced if the device is able to perform threshold checks automatically (especially for the LV lead with CRT devices). A second aspect is remote monitoring, with triggering of automatic alert messages in case of an LV threshold rise. Without an algorithm that automatically adjusts pacing output (such as the ‘adaptive’ mode of LVCM), the patient will require in-office device reprogramming.

**Study limitations**

The accuracy of the LVCM algorithm was not verified manually in our study, and fluctuations of LV thresholds may simply have been the result of measurement error. However, the algorithm is already validated and has been shown to be extremely precise in a recent report, where errors were found only in 0.6% of tests (due to PVCs falling into the capture detection window and as a result of atrial loss of capture during the conduction checks). Furthermore, by expressing threshold fluctuations as the trimmed mean (10th–90th percentile), the effect of outliers due to possible measurement error would have been minimized. The fact that the analysis using the trimmed mean gave almost identical results compared with entire weekly ranges indicates that outlier values were not an issue.

Automated LVCM measurements are performed at night, and may therefore not reflect daytime thresholds. However, in the study by Crossley et al., differences between the last night-time LVCM measurement and the in-office manual threshold was within one voltage step in 96.4% of patients. Although this does not rule out changes in threshold during exercise, it does suggest that circadian variations and also to some extent changes in threshold with posture are minor.

Our recommendations concerning programming of the LV safety margin refer to the period between the 1 and 6 month visits, and may not be applicable later on, or for longer follow-up intervals. However, LV thresholds and threshold fluctuations remained constant up to 12 months, and it is unlikely that recommendations should differ after the 6 month visit.

Our results are derived from Medtronic leads (essentially the 4193 and 4194 models), and may not be applicable to other leads with different characteristics and designs for stabilization.

Finally, as previously mentioned, the resolution of the LVCM threshold measurements was limited by the 0.5–1 V threshold steps. This may have led to overlap between categories of LV threshold fluctuations and also implies that the manually measured threshold should ideally be rounded off to the upper 0.5 V before adding the required safety margin to determine the pacing output.

**Conclusions**

While most patients with CRT show very little fluctuation in LV thresholds, there are individuals who show marked fluctuations, especially those patients with higher (>2.0 V) capture thresholds. The LVCM algorithm is useful for automatically adjusting the pacing output in case of threshold fluctuation, especially in patients with high LV thresholds (in order to avoid premature battery depletion) and in those with phrenic nerve stimulation (where low safety margins may be required). In devices without this feature, a 1.0 V safety margin may be empirically set if the LV threshold is low (<2.0 V), but a greater margin (e.g. double the threshold) may be necessary in case of high thresholds, due to wider day-to-day fluctuations.

**Conflict of interest:** H.B. has received research grants and has been on the speaker’s bureau for Medtronic and Boston Scientific. B.G., L.D., and M.D. are employees of Medtronic Inc. C.S. has received research grants and has been on the speaker’s bureau for Medtronic and Boston Scientific.

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