

Manual vs. automatic capture management in implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillators

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Aims

The Secura™ ICD and Consulta™ CRT-D are the first defibrillators to have automatic right atrial (RA), right ventricular (RV), and left ventricular (LV) capture management (CM). Complete CM was evaluated in an implantable cardioverter defibrillator (ICD) population.

Methods and results

Two prospective clinical studies were conducted in 28 centres in Europe and Israel. Automatic CM data were compared with manual threshold measurements, the CM applicability was determined, and adjustments to pacing outputs were analysed. In total, 160 patients [age 64.6 ± 10.4 years, 77% male, 80 ICD and 80 cardiac resynchronization therapy defibrillator (CRT-D)] were included. The differences between automatic and manual measurements were ≤ 0.25 V in 97% (RA CM) and 96% (RV CM) and were all within the safety margin. Fully automatic CM measurements were available within 1 week prior to the 3-month visit in 90% (RA), 99% (RV), and 97% (LV) of the patients. Results indicated increased output (threshold >2.5 V) due to raised RA threshold in seven (4.4%), high RV threshold in nine (5.6%), and high LV threshold in three patients (3.8%). All high threshold detections and all automatic modulations of pacing output were adjudicated appropriate.

Conclusion

Complete CM adjusts pacing output appropriately, permitting a reduction in office visits while it may maximize device longevity.

The study was registered at ClinicalTrials.gov identifiers: NCT00526227 and NCT00526162.

Keywords

Automatic pacing threshold • Capture management • ICD • CRT-D

Introduction

Capture management (CM) is a programmable feature that allows automatic adjustment of pacing amplitudes in response to changing pacing thresholds. It monitors whether pacing pulses capture the myocardium and, optionally, adjusts their amplitude to changing patient conditions. In CM operation, the device prepares for a

pacing threshold search, conducts the pacing threshold search, and determines the pacing threshold. Over time, the threshold measurements are collected to create threshold trends. If CM is programmed to 'Adaptive', the device may automatically adjust the pacing outputs. If CM is programmed to 'Monitor', no adjustments occur. Capture management has been featured in pace-makers for several years.

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The automatic right atrial (RA) and right ventricular (RV) CM features have been incorporated for the first time in high-power devices (Secura™ ICD and Consulta™ CRT-D). The Consulta CRT-D devices also have the previously validated automatic LV CM incorporated.¹

The algorithms included in Secura ICD and Consulta CRT-D devices are very similar to those included in recent Medtronic pacemakers. Automatic threshold measurements occur near 1 a.m. every day and will retry on half-an-hour intervals in the event of an unsuccessful measurement (e.g. if the intrinsic rhythm is fast or unstable). The algorithms measure thresholds based on progressively lowering test pace amplitudes, until loss of capture is determined. Right atrial CM determines atrial capture by application of a test pace to the atrium and evaluating either the response of the intrinsic rhythm or by evaluating the timing of the conducted ventricular response. Ventricular CM determines capture by applying a test pace to the RV and evaluating the timing of the evoked response signal. Left ventricular CM determines capture by applying a test pace to the LV and comparing the timing of a conducted response in the RV to predetermined A–RV and LV–RV conduction characteristics. After the loss of capture voltage has been determined, the algorithms confirm capture at the threshold amplitude of 0.125 V above the loss of capture voltage. When programmed to the Adaptive mode, pacing output amplitudes are adjusted automatically by applying the programmed safety margin to the measured threshold. For RA and RV CM, the safety margin is a multiple of the measured threshold (nominally, 2.0 for both RA and RV CM). The pacing output is therefore maintained at a voltage that is larger than the measured threshold by at least a factor of the safety margin. Right atrial and RV CM also each have a programmable minimum adapted amplitude (nominally, 1.5 V and 2.0 V, respectively) below which pacing output will never be automatically programmed. Right atrial and RV CM will not adjust pacing outputs >5 V with a 1.0 ms pulse width. Left ventricular CM uses a different safety margin, nominally 1.5 V above the measured threshold. Left ventricular CM also has a programmable maximum adapted amplitude such that potential stimulation concerns at high pacing outputs can be avoided.

There has been a long-standing concern about inappropriate high measurements based on the original CM algorithm.^{2–4} However, more recent generations incorporate features (such as the ability to switch sensing of the evoked response from bipolar to unipolar) that have mitigated this problem in pacemakers.⁵

Capture management will inevitably be increasingly important in the era of remote follow-up.^{1,6–7} As the number of patients with implantable cardiac devices continues to increase with current patient demographics, the need to reduce the follow-up burden increases.

The primary objective of the Secura and Consulta clinical studies was to evaluate the safety of these devices. A secondary objective was to evaluate the automated RA and RV CM features in high-power devices. The LV CM algorithm has already been validated in a previous CRT-D study¹ and therefore was not validated in the current clinical study.

In this manuscript, we report on the results of the first validation of the RA and RV CM algorithms in high-power devices, the

applicability of RA, RV, and LV CM, and the effects that RA, RV, and LV CM features have on pacing outputs.

Methods

Study design

Two separate prospective, multicentre, non-randomized clinical studies (Secura ICD and Consulta CRT-D) were conducted in 28 centres in Europe and Israel; see Appendix for a list of participating investigators. Both clinical studies were conducted in compliance with the Declaration of Helsinki, the research protocols were approved by the local Ethics Committees, and for all patients, informed consent was obtained prior to enrolment in the study.

The eligibility criteria were primarily designed to reflect current indications for implantable cardioverter defibrillator (ICD)/cardiac resynchronization therapy defibrillator (CRT-D) implantation.

Inclusion criteria

Patients with an established indication for ICD or CRT-D implantation according to international guidelines,^{8–9} or elective device replacement; who were receiving optimal medical therapy, and were geographically stable and available for follow-up. In addition for the Consulta study, patients receiving new implants who were in NYHA class III or IV and had intrinsic QRS duration >120 ms within 30 days prior to baseline; and LV ejection fraction (LVEF) ≤35% within 180 days prior to baseline (patients undergoing CRT-D unit replacement were assumed to have met these criteria at the time of original implant). Local Ethics Committee approval and written informed consent were obtained in all cases.

Exclusion criteria

Patients with a life expectancy less than the duration of the study; with medical conditions precluding the testing required by the study protocol or otherwise limiting study participation (including pregnancy and breastfeeding); with mechanical tricuspid heart valves; participating in any concurrent device study, or any drug study that might confound the results of this trial; in need of device replacement with lead integrity problems (and the lead(s) can or will not be replaced).

Manual threshold measurements were obtained at the 1-month follow-up and the automatic RA and RV CM data were compared with manual threshold measurements for all implanted subjects with a valid manual threshold test and a successful CM threshold measurement completed ≤2 days beforehand. The thresholds were determined by decreasing the amplitude in steps of 0.125 V (automatic) and 0.25 V (manual), respectively.

The CM algorithms were programmed to measure the threshold once per day. Applicability was defined as the percentage of patients who had successful threshold measurement over a given time period prior to the 3-month visit. Applicability was examined based on the data of the 3-month visit in subjects with device programming that allowed automatic threshold measurements. The 3-month follow-up was chosen for analysis because the maximum number of patients had device data for this period. Although CM applicability may be higher with more frequent measurement attempts,¹⁰ a daily measurement was chosen

as a trade-off between achieving the highest applicability without excessive measurement attempts. The CM applicability was determined for the following periods: 1, 3 days, 1 week, 1, and 3 months prior to the 3-month follow-up.

At the 6-month follow-up visit, automatic threshold data were analysed in patients with devices programmed to the Adaptive CM mode (RA, RV, and LV CM), to determine how often and in which direction the current CM algorithms adjusted the pacing outputs since the pre-discharge visit. The 6-month follow-up was chosen for this analysis to ensure that the leads had matured past the acute implant phase and that the CM algorithms had time to adjust the pacing outputs.

Statistical analysis

Descriptive statistics were performed to summarize the results of these analyses.

Data from the comparison between the manual threshold results and the automatic CM threshold results are presented as *n*, mean, standard deviation (SD), median, range, and 95% confidence interval. Capture management applicability is presented as absolute numbers. Data from the adjustment of the pacing output are represented as *n*, mean, SD, range, and percentages.

Results

Patient demographics

In total, 160 patients were successfully implanted and included in the two clinical studies. Those 160 patients had a mean age of 64.6 ± 10.4 years, 77% were male, mean LVEF was $27.6 \pm 9.6\%$, 80 were ICD, and 80 were CRT-D patients. Of the 160 patients, 42 (26%) had atrial fibrillation (AF) at baseline with 24 paroxysmal AF, 9 persistent AF, and 9 permanent AF. The CRT-D and the ICD patient groups had similar demographics and device threshold data (Table 1).

Table 1 Patient demographics

Number of subjects	160
Age (years), mean (SD)	64.6 ± 10.4
Male	123 (77%)
Myocardial infarction	90 (56%)
Atrial fibrillation	42 (26%)
Paroxysmal AF	24
Persistent AF	9
Permanent AF	9
NYHA class II	30 (19%)
NYHA class III	113 (71%)
NYHA class I, IV	8 (5%)
Beta-blocker	139 (87%)
ACE-inhibitor	140 (88%)
Diuretics	124 (78%)
No heart failure	6 (4%)
LVEF (%), mean (SD)	27.6 ± 9.6
Ischaemic cardiomyopathy	90 (56%)

Manual vs. automatic capture management

Table 2 details 1-month paired (manual and CM) data that were available for 159 patients including 114 paired atrial measurements and 139 paired RV measurements. The combined results showed that for RA and RV CM, respectively, 86 and 84% of automatic measurements were within 0.125 V of the manual measurement, 97 and 96% were within 0.25 V of the manual measurement, and 100 and 99.3% were within 0.5 V. All differences were well within the standard two-fold safety margin for output automatically set by the device (Figures 1 and 2).

Capture management algorithm applicability

The CM applicability was measured at 1, 3 days, 1 week, 1, and 3 months prior to the 3-months follow-up visit. Right atrial CM applicability was 119 of 135 (88%), 122 of 135 (90%), 122 of 135 (90%), 122 of 135 (90%), and 125 of 134 (93%) when measured within 1, 3 days, 1 week, 1, and 3 months, respectively. The RV CM applicability was 141 of 144 (98%), 142 of 144 (99%), 142 of 144 (99%), and 143 of 144 (99%) when measured within 1, 3 days, 1 week, 1, and 3 months, respectively. The LV CM applicability was 62 of 68 (91%), 62 of 68 (91%), 66 of 68 (97%), 66 of 68 (97%), and 66 of 68 (97%) when measured within 1, 3 days, 1 week, 1, and 3 months, respectively. Of the 16 patients without an atrial threshold measurement within 1 day, 8 were due to persistent atrial tachycardia/AF, 5 were due to significant pacemaker dependence (i.e. nearly 100% atrial and ventricular paced), and 3 were due to high or variable rates. The lack of RV and LV measurements were due to a competing rhythm. Competing rhythms can occur due to high or variable intrinsic rate or short AV. These results are consistent with previous studies in pacemaker⁵ and CRT-D patients.

The RA and RV CM algorithms indicate a 'high threshold' when the measured threshold is >2.5 V. In these cases, when programmed to the Adaptive mode, the algorithm adjusts pacing output to 5 V with a 1.0 ms pulse width. The CM results based on 160 patients indicated high RA threshold in seven patients (4.4%) and high RV threshold in nine patients (5.6%). Because LV thresholds tend to be higher than A and RV thresholds, the LV CM algorithm will measure thresholds up to 6.0 V. The LV CM results based on 80 patients indicated that the algorithm was unable to maintain the programmed safety margin due to high thresholds in three patients (3.8%) at some point prior to the 6-month follow-up.

All of these indications of high thresholds were due to appropriate measurement of high thresholds (five patients), lead dislodgements (four patients), acute effects of lead maturation (six patients), or incomplete connection of the lead in the header block (one patient).

Pacing output

Right atrial, RV, and LV CM were programmed to the Adaptive mode with 6 months of follow-up data in 133, 132, and 51 devices, respectively. The CM adapted pacing outputs were compared with the clinician programmed pre-discharge pacing

Table 2 Automatic threshold measurements (CM) vs. manually determined threshold

	Automatic threshold	Manual threshold	Difference, CM – manual
RA threshold (n = 114)			
Mean ± SD	0.713 ± 0.242	0.730 ± 0.231	-0.018 ± 0.141
Median	0.625	0.750	0.000
Range	0.250–1.625	0.250–1.500	-0.500–0.375
95% CI	0.668, 0.758	0.687, 0.773	-0.044, 0.009
RV threshold (n = 139)			
Mean ± SD	0.843 ± 0.430	0.885 ± 0.425	-0.042 ± 0.147
Median	0.750	0.750	0
Range	0.375–2.500	0.250–2.250	-0.500–0.625
95% CI	0.771, 0.915	0.814, 0.956	-0.067, -0.018

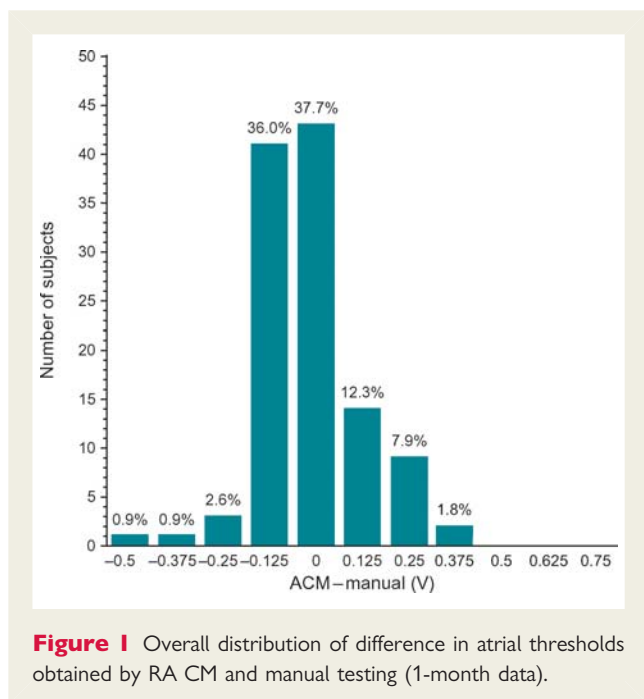


Figure 1 Overall distribution of difference in atrial thresholds obtained by RA CM and manual testing (1-month data).

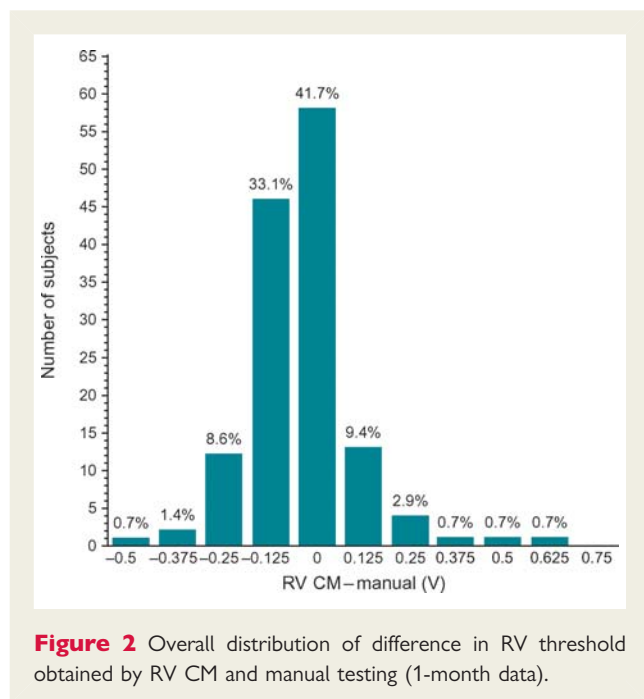


Figure 2 Overall distribution of difference in RV threshold obtained by RV CM and manual testing (1-month data).

outputs (in a majority of cases, the pre-discharge pacing output was the pacemaker nominal setting). Capture management increased the RA output in four patients (3.0%), increased the RV output in nine patients (6.8%), and increased the LV output in one patient (2.0%). The maximum output increase in each chamber was 1.5 V. Capture management decreased the RA output in 112 patients (84.2%), decreased the RV output in 115 patients (87.1%), and decreased the LV output in 49 patients (94.2%). For ICD subjects, the mean decreases in RA and RV were 1.7 and 1.1 V, respectively. For CRT-D subjects, the mean decreases in RA, RV, and LV were 1.2, 1.2, and 1.4 V, respectively. Overall, the output decreased >1 V in each chamber: the mean decreases in RA, RV, and LV were 1.5, 1.2, and 1.4 V, respectively (Table 3). All adjustments were found to be appropriate when CM and manual threshold measurements were examined.

Discussion

This study demonstrates that the CM algorithms perform as intended, reducing or increasing pacing outputs where appropriate without compromising the safety margin. The CM algorithms adjust the RA, RV, and LV pacing outputs appropriately and only in response to true changes in the patients' pacing thresholds. The inappropriate adjustments to high pacing outputs that were occasionally observed in earlier pacemakers were not observed in this study. All of the indications of high output were due to appropriate measurement of high threshold caused by chronic high thresholds, lead dislodgements, acute effects of lead maturation, or incomplete connection of the lead in the header block.

The differences that were seen between CM threshold data and manual threshold data in this study may be explained by:

Table 3 Comparison between the amplitude at pre-discharge and at the 6-month follow-up visit

Amplitude (V)		RA CM (n = 133)	RV CM (n = 132)	LV CM (n = 51)
Mean ± SD	Implant	3.5 ± 0.5	3.5 ± 0.4	4.0 ± 0.5
	6-Month	2.0 ± 0.8	2.3 ± 0.7	2.6 ± 0.7
	Difference (6-month – implant)	–1.5 ± 0.9	–1.2 ± 0.8	–1.4 ± 0.8
Range	Implant	2.0–5.0	2.0–5.0	2.25–6.0
	6-Month	0.5–5.0	1.5–5.0	1.75–5.5
	Difference (6-month – implant)	–3.5 to 1.5	–3.0 to 1.5	–3.5 to 1.5
No. of amplitude decreases from implant to 6-month (n, %)		112 (84.2)	115 (87.1)	49 (96.1)
No. of amplitude increases from implant to 6-month (n, %)		4 (3.0)	9 (6.8)	1 (2)
No. of unchanged amplitudes from implant to 6-month (n, %)		17 (12.8)	8 (6.1)	1 (2)

- (i) Normal and circadian variation; although threshold variation is typically quite low, because the measurements were taken at different points in time, there is some normal variation that can occur.^{7,10}
- (ii) Manual thresholds are performed using 0.25 V threshold steps, whereas the automatic thresholds use 0.125 V steps. When all other variables are equal, this difference in step size will result in manually measured thresholds that are on average slightly larger than automatically measured thresholds. This accounts for the slight left shift in the data presented in *Figures 1 and 2*.

The CM features in the Consulta CRT-D and the Secura ICD provide daily confirmation of pacing capture and appropriate maintenance of patients' safety margins while avoiding adverse effects. The adjustments to pacing outputs can maximize battery longevity in patients who require pacing. In addition, cost-effectiveness may increase as the number of clinic visits reduces, and the time required for follow-up visits may decrease. At the same time, reliable CM allows for an increase in the number of remote device follow-ups, which may add to cost-effectiveness.^{11–18}

Conclusion

This study demonstrates that the RA and RV CM algorithms performed as intended. The CM algorithms adjust the RA, RV, and LV pacing outputs appropriately and only in response to changes in the patients' pacing thresholds. Complete CM reliably and safely manages pacing outputs, may reduce the number of routine in-office visits, and may maximize battery life.

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Conflict of interest: J.M.-H. and Y.C. are both employees of Medtronic. F.D.M. is an advisory board member for Medtronic. C.M. received honoraria as speaker for Medtronic, Biotronik, and Bard.

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Appendix

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