

Ventricular Capture Management™ in pediatric pacing: efficacy and safety

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Background. The Ventricular Capture Management™ (VCM) of Medtronic Kappa 700 series pacemakers (PM) performs automatic threshold detection and optimization of pacing output that may enhance generator longevity. We evaluated efficacy and safety of this algorithm in children.

Methods. The study was prospective, non-randomized, involving 50 consecutive patients (mean age 5.6 ± 6.6 years, median 4 years), enrolled at first PM implant. VCM was active from the implant, with nominal values of safety margin, minimum adapted pulse amplitude and width. Leads were endocardial and epicardial, all unipolar. Thresholds and pacing outputs were registered with telemetric PM interrogation. Endocardial and epicardial thresholds and outputs were also compared. Follow-up duration was 27 ± 13 months (range 6-49 months).

Results. A significant reduction in pulse amplitude was evident since the sixth month. Thresholds and outputs were lower in endocardial than in epicardial pacing. A false negative capture detection occurred during the "acute phase" in 3 patients (6.0%), with incorrect automatic output increase to 5 V/1 ms. After this phase, the problem was still detected in 2 patients (4.0%). VCM correctly identified threshold increases in 2 patients (1%). No pacing defect was documented. VCM was not performed in 4 infants (8.0%) for pacing rate ≥ 100 b/min.

Conclusions. VCM function is safe and effective in reducing pacing output in pediatric patients; this may increase PM longevity. Epicardial pacing shows higher thresholds and outputs than endocardial pacing.

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Introduction

Children and adolescents with permanent pacemaker (PM) need repeated PM generator replacements throughout their life. Their active lifestyle combined with the higher rate of pacing at younger ages may reduce the PM generator life. The development of pacing systems with automatic threshold detection and automatic optimization of voltage output may reduce current drain and enhance pulse generator longevity¹⁻¹³. The Ventricular Capture Management™ (VCM), available in Medtronic Kappa 700 and 900 series PMs (Medtronic, Minneapolis, MN, USA), performs an automatic threshold search. Although programmable, it usually is performed once a day, at rest. The programmed safety margin determines pacing output. A false negative detection of capture sometimes occurs because of undersensing of the evoked response. In this case, the device incorrectly increases the pacing output. A false positive detection of capture might occur if the device incorrectly reduces pacing output due to oversens-

ing of the evoked responses. This algorithm may also work in "monitor only" mode in which the pacing search is performed without output adjustment. Recently, a paper demonstrated "acceptable VCM performance in monitor only mode" in children and young adults¹³. The aim of this work was to evaluate the efficacy and safety of VCM in a cohort of pediatric patients who underwent a first PM and lead implantation with this algorithm activated in all patients just after enrolment and not only after the "acute phase".

Methods

The study was prospective, non-randomized, involving all patients who underwent a first PM and lead implantation with Medtronic Kappa 700-701 SR and DR PM at the Bambino Gesù Pediatric Hospital. All patients were enrolled at initial implant of PM and leads. The ventricular thresholds were measured at the time of lead implant with the Medtronic Pacing System Analyzer model 5311 B. In the Kappa PM the

VCM was by default active from the moment of the implant, with nominal values of safety margin and minimum adapted pulse amplitude and width. The programmed safety margin determines pacing output: in the Kappa 700 PMs nominal values are $1.5 \times$ voltage threshold, minimum adapted pulse amplitude is 2.5 V, and minimum adapted pulse width is 0.40 ms. The ventricular capture test was performed daily by the PM, usually at night-hour. However, during "acute phase" thresholds cannot be automatically adjusted down. During follow-up visits, performed at 1, 3, 6, and then every 6 months, or as needed, the automatic thresholds and the automatically adapted pacing pulse amplitudes and widths were obtained with telemetric interrogation of the Kappa PM with the Medtronic 9720 programmer. At each follow-up visit, standard ECG and clinical evaluation were performed in each patient. During PM interrogations, especially in the first visits, a manual measure of threshold (strength-duration curve) was performed to verify if the automatic threshold measurement was correct. All thresholds reported were calculated at 0.40 ms of pulse duration. Pulse amplitude and duration at different times were compared. Patients were also divided according to epicardial or endocardial pacing, and pacing outputs and thresholds were compared, to evaluate the VCM function in these subgroups. Holter monitoring was performed every 6 months in each patient, as part of our routine follow-up in children with congenital heart disease and/or permanent PM.

Statistical analysis. Data are expressed as mean \pm SD. The median was specified when described. Statistical analysis was performed with the Student's t-test for continuous variables and with the χ^2 test for nominal variables. A p value of < 0.05 was considered as statistically significant.

Results

Totally, 50 consecutive patients (33 males, 17 females) were implanted with a Medtronic Kappa 701 SR

and DR PM between June 1998 and July 2002. Data of patients are reported in table I. VCM analysis for this study was performed until the end of 2002.

Pacing mode was VVI in 4 patients, VVIR in 20 patients, DDD in 21 patients, and DDDR in 5 patients. Leads implanted are Medtronic 4023 (endocardial) and 4965 (epicardial), all unipolar, steroid-eluting; endocardial leads are tined (passive fixation). A total of 593 telemetric PM interrogations were performed. Automatic and manual thresholds were not significantly different, as already reported in the literature¹¹. Threshold values were relatively stable during the follow-up, that was 27 ± 13 months (range 6-49 months). From the third month, pulse amplitude was lower (Table II). This early output reduction was manually performed when the thresholds were particularly low. The reduced pulse amplitude became more evident after the third-sixth month, when the "acute phase" (112 days) ended and the PM started the automatic reduction of the pacing output according to the measured threshold.

Thresholds measured in 23 patients (6 females) aged 2.9 ± 4.9 years (median 1 year) with steroid-eluting epicardial leads were always significantly higher

Table I. Patient characteristics.

No. patients	50
Age at implant (years)	5.6 ± 6.6 (median 4)
Arrhythmia	
Congenital-acquired AVB	24
Paroxysmal AVB	4
Post-surgical AVB	17
Sinus node dysfunction	5
Heart disease	
VSD/AVSD	15
UVH, Fontan operation	4
Tetralogy of Fallot	4
Cardiomyopathy	3
Other	4
None	20

AVB = atrioventricular block; AVSD = atrioventricular septal defect (AV canal); UVH = univentricular heart; VSD = ventricular septal defect.

Table II. Pacing thresholds and output values.

	Thresholds (V)	Pulse amplitude (V)	Pulse duration (ms)	No.
Implant	0.8 ± 0.5	4.0 ± 0.9	0.45 ± 0.12	50
1 month	0.7 ± 0.4	3.8 ± 0.9	0.47 ± 0.13	48
3 months	0.8 ± 0.5	$3.4 \pm 1.2^*$	0.43 ± 0.07	23
6 months	0.9 ± 0.5	$2.8 \pm 0.6^*$	0.41 ± 0.03	26
12 months	0.8 ± 0.4	2.8 ± 0.7	0.43 ± 0.11	34
18 months	0.8 ± 0.3	2.8 ± 0.8	0.45 ± 0.16	26
24 months	0.9 ± 0.6	2.8 ± 0.6	0.44 ± 0.20	23
30 months	0.9 ± 0.5	2.8 ± 0.6	0.44 ± 0.09	19
36 months	0.8 ± 0.4	2.7 ± 0.4	0.44 ± 0.07	14
42 months	0.8 ± 0.4	2.6 ± 0.1	0.42 ± 0.03	6

* p < 0.05 between groups.

than in 27 patients (16 males, 11 females) aged 8.8 ± 7.1 years (median 7 years) with endocardial leads (Fig. 1, Table III). Pulse duration did not significantly differ between these patients; pulse amplitude was lower in endocardial pacing but this difference was significant only at implant, and at 12 and 24 months, as the amplitude values are very close to the minimum adapted value (2.5 V/0.40 ms) (Fig. 1, Table III).

Thresholds were not automatically analyzed in 4 neonates and infants (8.0%) because of high pacing rate (≥ 100 b/min) of the DDD PM.

A false negative detection of capture occurred in 3 patients (6.0%), 2 with Medtronic 4023 leads and one with Medtronic 4965 lead, during the ‘‘acute phase’’: the device incorrectly increased the pacing output to 5 V/1.0 ms. The device was then programmed to the ‘‘monitor only’’ mode in 2 patients. After the sixth month, in the patient with epicardial pacing the device was reprogrammed in adaptive mode and the VCM worked correctly. In the third patient (4023 lead) the VCM was left

in adaptive mode because the patient had irregular follow-up, and the incorrect detection of capture continued. Thus, after the ‘‘acute phase’’ one patient was in ‘‘monitor only’’ mode and another one with VCM on, still showed false negative detection of capture. In 2 patients the device correctly identified an increase of threshold and the ventricular output was increased: in one patient with Medtronic 4965 lead the threshold increased from 1.3 V (6 months) to 2 V and 2.6 V (12 and 24 months, respectively); in the other (4023 lead), the analysis of device memory showed that threshold rose from 0.65 V (0.40 ms) at 30-month interrogation (output 2.6 V/0.52 ms) to 2.3 V (0.40 ms, output 5 V/0.64 ms) and then decreased to 0.7 V (0.40 ms) at 36-month interrogation (output 4 V/0.64 ms) (Fig. 2).

No patient showed pacing defect due to false positive detection of capture. None of our patients was PM-dependent, but all patients, except those with paroxysmal atrioventricular block (in whom pacing mode was VVI) were continuously paced: the percentage of ventricular pacing (as results from device interrogation and Holter monitoring) was $> 90\%$.

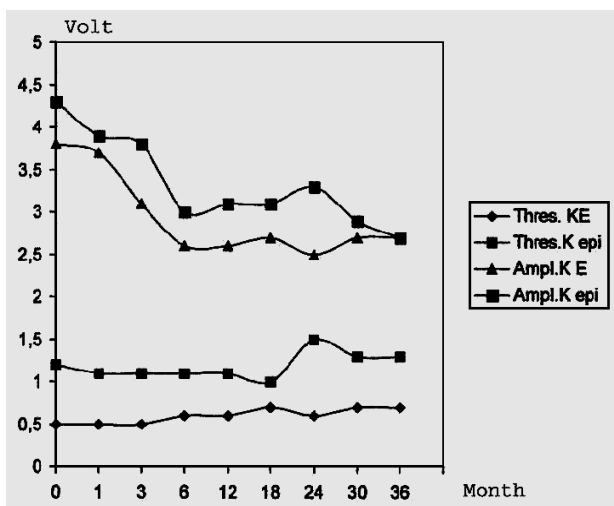


Figure 1. Comparison of average thresholds and amplitudes in endocardial (E) and epicardial (epi) pacing.

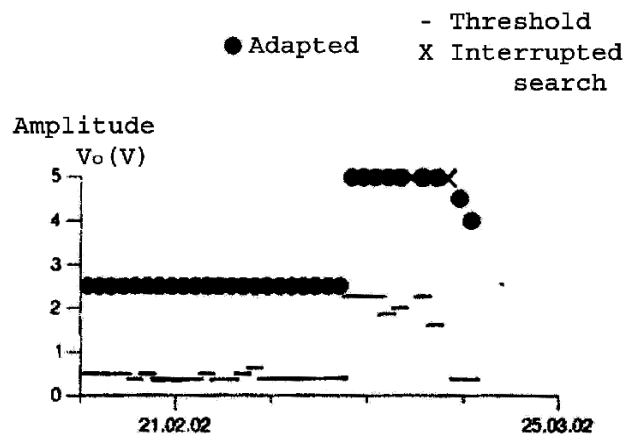


Figure 2. Telemetric interrogation of a Kappa pacemaker which shows the correct detection of threshold increase and the automatic pacing output increase.

Table III. Comparison of endocardial and epicardial pacing thresholds and outputs.

	Thresholds		Endocardial leads			Epicardial leads		
	Endocardial	Epicardial	Amplitude (V)	Duration (ms)	No.	Amplitude (V)	Duration (ms)	No.
Implant	$0.5 \pm 0.3^*$	$1.2 \pm 0.4^*$	$3.8 \pm 0.9^*$	0.46 ± 0.15	27	$4.3 \pm 0.8^*$	0.44 ± 0.06	23
1 month	$0.5 \pm 0.2^*$	$1.2 \pm 0.4^*$	3.7 ± 1.0	0.47 ± 0.16	27	4.0 ± 0.9	0.46 ± 0.08	20
3 months	$0.5 \pm 0.1^*$	$1.2 \pm 0.5^*$	3.1 ± 1.4	0.41 ± 0.03	12	3.6 ± 0.9	0.45 ± 0.08	11
6 months	$0.6 \pm 0.6^*$	$1.1 \pm 0.2^*$	2.6 ± 0.4	0.40 ± 0.02	14	2.8 ± 0.4	0.41 ± 0.04	12
12 months	$0.6 \pm 0.3^*$	$1.1 \pm 0.4^*$	$2.6 \pm 0.2^*$	0.41 ± 0.04	20	$2.9 \pm 0.8^*$	0.45 ± 0.17	14
18 months	$0.7 \pm 0.3^*$	$1.1 \pm 0.4^*$	2.7 ± 0.6	0.44 ± 0.15	17	3.0 ± 0.9	0.49 ± 0.22	9
24 months	$0.6 \pm 0.3^*$	$1.5 \pm 0.6^*$	$2.5 \pm 0.1^*$	0.44 ± 0.09	14	$3.1 \pm 0.8^*$	0.45 ± 0.12	9
30 months	$0.7 \pm 0.4^*$	$1.3 \pm 0.4^*$	2.7 ± 0.6	0.45 ± 0.11	12	2.9 ± 0.7	0.41 ± 0.02	7
36 months	$0.7 \pm 0.4^*$	$1.3 \pm 0.2^*$	2.7 ± 0.5	0.44 ± 0.08	11	2.7 ± 0.5	0.40 ± 0.00	3

* $p < 0.05$ between groups.

Discussion

Technical evolution made pediatric pacing easier, safer and more effective; new leads and generators substantially improved the outcome of pacing¹⁴⁻¹⁹. Most problems are still related to the long-term outcome of the leads and to body growth^{14,18,19}; furthermore, many generator replacements are expected in pediatric patients. Threshold measurements during routine follow-up telemetric interrogation are time-consuming and not always routinely performed. Moreover, often output values are not reduced by clinicians for caution, and a substantial percentage of the PMs implanted remain at the nominal setting after the implant²⁰.

The VCM, available in Medtronic Kappa 700 and 900 series PMs (Medtronic, Minneapolis, MN, USA) and the Autocapture™ function, available in some of St. Jude PMs (St. Jude Medical, Sylmar, CA, USA) are clinically utilized in ventricular pacing to automatically adapt pacing outputs to measured thresholds. These functions have been shown to be effective in children^{1,2,13} and adults³⁻¹², although problems with these algorithms that may have potentially serious consequences have been described^{13,21}. A third automatic ventricular capture system with a beat to beat analysis, working with any lead and any polarity is available in a recent PM manufactured by Guidant (Insignia™ Ultra), but no data have been published in the literature.

The VCM algorithm of Medtronic Kappa 700 PM was designed to improve pacing therapy by adjusting pacing output to thresholds measured and safety margins programmed, which, in turn, might affect PM longevity and reduce replacement procedures and the costs of pacing therapy. The value of this algorithm derives also from its automaticity, allowing a constant update and adaptation to the patient's needs²⁰.

These results, in a large pediatric population with unipolar leads implanted at the same time of the Kappa PM and with the VCM activated in all patients just after enrolment, demonstrate that the VCM function is effective, safe, and helpful in reducing energy consumption either in endocardial or in epicardial pediatric pacing. The VCM function may work with unipolar and bipolar leads, while the Autocapture™ algorithm needs bipolar leads. In pediatric pacing unipolar leads are often preferred for their smaller size that may reduce the risk of venous occlusion in endocardial pacing²². In epicardial pacing the smaller dimensions of unipolar leads make technically easier their implantation in the small hearts of neonates and infants and in presence of large scars on the epicardium as in patients with previous heart surgery. The majority of our patients with Kappa PM were paced at output values < 3.0 V/0.50 ms (Fig. 1). This should improve PM longevity, that may be calculated as an additional longevity extension of 7-12 months^{13,20}, without impairing safety: the lower limit of 2.5 V/0.4 ms is significantly over the average threshold. Moreover, the algorithm was effective in ad-

equately increasing the pacing outputs in patients with threshold increase (1% of our population).

During follow-up, signs and symptoms of capture loss or pacing defects (due to false positive detection of capture) were never documented: constant ventricular capture was demonstrated with PM interrogation, ECG and Holter monitoring (Fig. 3). This is an important finding, since the VCM function does not deliver back-up pulses in case of loss of capture except during the threshold search (Fig. 3). Furthermore, the device usually performs the pacing threshold search during the night, at rest. It has been demonstrated in adult subjects that during sleep the ventricular thresholds tend to be higher; thus, pacing output values set during the night may have wider safety margins in the daytime²³. Undersensing of the evoked response has been described in 3.4% of adult¹² and in 6.7% of pediatric patients¹³ and in a case report²¹. In the study of Cohen et al.¹³, conducted with VCM programmed in "monitor only" mode, successful evoked response detection was observed in 100% of endocardial leads and in 87% of unipolar epicardial leads. In our data, a false negative detection of capture occurred in 6.0% of patients, and might be partially related to the "lead maturation" (time after the implant), as in one patient the incorrect detection was not documented after the sixth month. Thus, in these patients with incorrect capture detection, the VCM may not be useful in the "acute phase". In 2 patients (4.0%) this problem continued after the "acute phase" and would result in inappropriate high pacing output and early battery depletion. This is a particularly low rate of false negative detection of capture, and might be related to the homogeneity of the population described (first implantation, unipolar leads). In 8.0% of subjects the high pacing rate excluded the application of this function for the first 1-12 months.

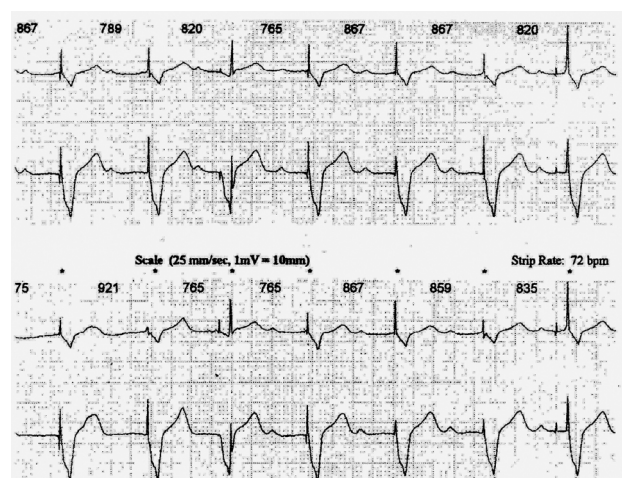


Figure 3. Holter monitoring during ventricular capture test, that is performed every 3 beats, in a patient with a VVIR pacemaker: ventricular capture is obtained (third beat of the strips) or not (seventh beat). Note the back-up pulse delivered by the device in both cases.

During follow-up, automatic thresholds measured in endocardial and epicardial pacing showed some fluctuations (Fig. 1, Table III) that may be caused by the electrode-tissue interface maturation²³. Ventricular thresholds were always lower in endocardial pacing than in epicardial pacing with steroid-eluting leads. Accordingly, pulse amplitudes in endocardial pacing were lower than in epicardial pacing. Although patients with endocardial and epicardial pacing differed by age, this evaluation showed the effectiveness of VCM also in these subgroups.

Study limitations. It is not a controlled study, so the real impact in terms of longevity was not verified. An estimation of the longevity saving on the basis of the difference between the actual and the nominal energy consumption was not calculated.

Except for the first visit in the first month, the number of patients evaluated at every follow-up visit was quite low (about 50% of the study population) and only few patients had a follow-up > 2 years.

The absence of PM-dependent patients might limit the evaluation of the efficacy and safety of the algorithm, but we have to underline that the great majority of our patients were continuously paced and episodes of pacing defect would have been detected during follow-up visits.

In conclusion, in pediatric patients with unipolar endocardial and epicardial leads implanted at the same time as the Kappa PM, the automatic VCM function of Medtronic Kappa 700 series PM was shown to be safe and effective in reducing pulse output close to the programmed minimum limit. This should result in increased generator longevity.

In 8.0% of patients the VCM could not be utilized because of elevated pacing rate.

The algorithm identified a threshold increase in 1% of patients and correctly adapted pacing outputs to the measured values. In the absence of VCM, this threshold increase in presence of a fixed pacing output might have caused pacing defect, as shown in figure 2. No pacing defect due to false positives was demonstrated. A false negative detection of capture was documented during the "acute phase" in 6.0% of patients, with consequently high pacing output not related to the real threshold. After the sixth month this problem was documented only in 4.0% of subjects that is a particularly low rate of false negatives. Despite this low rate, it is still necessary to verify the detection of capture to compare the manual with the automatic threshold during follow-up visits as in some patients with VCM activated and not properly evaluated during follow-up visits there is the risk of an early battery depletion. Therefore, we think that VCM function is useful in pediatric pacing and may be preferred to "conventional" systems with fixed outputs despite its cost, some cases of false negative detection, and the need for accurate controls.

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