Capture management efficacy in children and young adults with endocardial and unipolar epicardial systems


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Abstract  Aims  This prospective study characterized performance of the Kappa 700 Ventricular Capture Management™ (VCM) system for monitoring ventricular pacing threshold and adapting outputs in both endocardial and unipolar epicardial pacing systems in children and young adults. VCM bears cautionary labelling against use with epicardial leads since they have not been demonstrated appropriate for use with VCM.

Methods and results  VCM was programmed in "Monitor Only" mode. Ventricular pacemaker thresholds were measured daily using VCM for a minimum of 2 months. Potential device longevities at nominal outputs (3.5 V, 1.0 ms) and at VCM-recommended outputs were compared. Thirty patients (median age 14.4 years (1–27 years); 15 epicardial/15 endocardial) completed the study. During the daily measurements, consistent undersensed evoked response occurred in 2 patients (Medtronic epicardial leads 4965). For the other 28 patients, programming VCM in "Adaptive" mode from implant would provide an additional 6.8 months (0–19 months) of battery life.

Conclusion  Although not an IDE (Investigation Device Exemption) study, this study showed acceptable VCM performance in "Monitor Only" mode in 13/15 patients with unipolar epicardial leads. A 2-month "Monitor Only" observation period helps screen patients who might not benefit from VCM. VCM may provide substantial energy savings and extended battery life for children and young adults.

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KEYWORDS  pacemaker; children; evoked response; epicardial; Ventricular Capture Management
Introduction

Pacing system advances have evolved toward optimizing patient safety while at the same time maximizing device longevity. These have included improved electrode design with steroid-eluting leads and a more favourable geometry to reduce threshold rises and battery depletion [1–5]. Recently, advances in automatic pacemaker algorithms that can verify myocardial capture upon the detection of the evoked response have been shown not only to reduce, often time-consuming, office visits but also to promote battery longevity [6–9]. Because the polarization and evoked response on unipolar epicardial leads had not been well studied and because some capture detection systems require a bipolar lead it has been recommended that automatic capture detection be avoided in epicardial systems (mostly unipolar) and used strictly with either an endocardial or bipolar epicardial implant [6,10]. Unfortunately many children are either too small for an endocardial implant or have significant congenital heart defects that render a transvenous system impossible [11]. While anecdotal cases have demonstrated successful use of automated evoked response capture detection in children with steroid-eluting bipolar epicardial leads, implantation of a bipolar epicardial lead is often not practical in children and young adults with congenital heart disease because of either limited viable epicardial tissue or available space to affix two epicardial leads [12,13]. Thus there is a need for a pacing device to detect ventricular capture automatically from a unipolar epicardial lead.

Ventricular Capture Management™ (Medtronic, Inc., Minneapolis, MN, USA), a feature of Kappa 700 and 900 pacemakers, provides monitoring of ventricular pacing threshold with adaptive capabilities to enhance device longevity. VCM does not require a bipolar lead. VCM currently bears cautionary labelling against use in patients with epicardial leads because the safety and efficacy of VCM with epicardial leads had not been assessed. This prospective study was designed to characterize performance of the currently employed Kappa 700 Ventricular Capture Management system in "Monitor Only" mode in both endocardial and unipolar epicardial pacing systems in children and young adults.

Methods

Study population

Between June 2001 and December 2002, patients with a Medtronic Kappa 700™ pacemaker with a ventricular epicardial or endocardial lead were prospectively enrolled. As approved by The Children's Hospital of Philadelphia Committee for Protection of Human Subjects, each patient if ≥18 years of age or parent/legal guardian if <18 years of age signed a consent form prior to participation in the study. Demographic data regarding age, sex, congenital heart defect(s), type of prior heart surgeries, medication(s), and a detailed history of all pacing systems including leads and implantable generators were acquired from the pacemaker database at The Children's Hospital of Philadelphia.

Inclusion and exclusion criteria

Patients had to have had a ventricular lead implanted for at least 1 month with pacing thresholds less than 5 V/1.0 ms.

Study design

As a general overview, VCM provides automatic monitoring of ventricular pacing thresholds by performing a pacing threshold search to find an approximation of the patient's current rheobase (amplitude threshold at 1 ms) and chronaxie (pulse duration threshold at twice the rheobase voltage) values. Capture is determined based on detection of an evoked response during the 110 ms window following a test pace. Every test pace is followed by a backup pace at programmed amplitude 110 ms later. The ventricular pacing threshold search will abort if conditions are not right for running the search, including high intrinsic rate, or if capture at 0 V or noncapture at 2.5 V is detected, indicating possible erroneous measurements or high thresholds. In order to account for maturational changes in the lead, Kappa 700 devices continue to allow the physician to control the lower limit of pacing output and establish an "acute phase period" in which the pacemaker can only increase, not decrease, the pacemaker output.

Patients who achieved the above inclusion criteria underwent VCM threshold determination at their next routinely scheduled office visit and had their pacemaker programmed to a "Monitor Only" mode to allow the pacing threshold search to be performed once daily at 3 a.m. without outputs adjusted. Ventricular Capture Management threshold testing can only be performed at a heart rate <100 bpm. For those patients with a sinus rate >100 bpm (i.e. anxious or crying) at their initial office visit, VCM was programmed to "Monitor Only" with the belief that at home during the 3 a.m. test
hour the patient’s intrinsic rate would be <100 bpm. In addition, Capture Management detail was activated as a clinician-selected diagnostic guide to aid in the interpretation of the daily at-home threshold testing.

Patients were instructed to attend follow-up in 2–3 month’s time to uplink the device data. During the follow-up period the patient/family kept a diary of any illnesses (i.e. fever) that may have occurred to explain any unusual rise in VCM thresholds. At follow-up, the device was interrogated for daily VCM thresholds and a record of any aborted measurements due to high intrinsic rates, noise version, or undersensing of the evoked response limiting successful application of the VCM feature. The most recent VCM threshold and electrogram information were also collected and saved to disk for later analysis. Threshold testing by VCM was performed and Capture Management was turned “Off” thus completing the study.

Statistical analysis

All data are represented as either mean with standard deviation or median with ranges. Battery longevity savings are based on a previously reported mathematical model which calculates static current drain and pacing current drain based on the percentage atrial or ventricular paced, battery model (single versus dual chamber), pacing mode, mean heart rate, atrial and ventricular amplitude, pulse duration, and lead impedance [14]. Estimated longevity savings were based upon VCM-recommended outputs with a 1.5× safety margin and 2 V/0.21 ms minimum. Longevity savings were calculated using the assumption that thresholds would remain constant at the level measured at the return follow-up. The correlation of estimated longevity savings with patient age and also with mean heart rate were calculated.

Results

Study population

A total of 35 patients met inclusion criteria and were enrolled in the study. Of these 35 patients initially enrolled, 30 (86%; 18 females, 12 males) returned for the minimum 2-month follow-up visit and formed the investigational cohort. The median age was 14.4 years (1.29–27.3 years). Ten of the 30 patients were ≥18 years of age and were being followed by a pediatric cardiologist because of complex congenital heart disease. The median time from pacemaker implant to enrolment was 7.2 months (1.1–35.7 months). Twenty-six of the 30 patients had their ventricular lead implanted at the same time as the Kappa generator with the remaining 4 having their ventricular lead (2 epicardial; 2 transvenous) implanted 1.6–8.4 years preceding the new generator. Congenital heart disease was present in 20 (67%) patients as detailed in Table 1. Unipolar epicardial leads were used in 15 patients (4.84 years, range 1.29–20.6 years), bipolar endocardial leads in 14 patients, and a unipolar endocardial lead in 1 patient. Epicardial leads were used for a variety of clinical reasons including: small patient size (n = 3), single ventricle anatomy (n = 8), electively placed at the time of concomitant congenital heart surgery (n = 3), and as a result of SVC obstruction with a residual intracardiac shunt (n = 1). Ten patients had tined leads (Medtronic 5038, 4024, 4092) and 5 had active fixation leads (Medtronic 5076, 4557, 5068). The indications for pacemaker implantation included: sinus node dysfunction (n = 14, 47%), complete AV block (n = 11, 35%), and high-grade AV block (n = 5, 16%). Seventeen patients had DDD/DDDR systems; 8 patients had VDD systems; 5 had VVI/ VVIR systems. There was no significant difference in the energy threshold1 from lead implant (0.69 ± 0.98 μJ) to study enrolment (0.67 ± 1.1 μJ) and completion (0.42 ± 0.64 μJ, p = NS).

Chronic Ventricular Capture Management performance

Patients were monitored for a median of 95 days (range 56–285 days). Chronic success of VCM testing occurred in 28 (94%) of the patients. The percentage of ventricular pacing beyond the daily

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<td>s/p = status post, AV = atrioventricular.</td>
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1 Energy threshold: [(voltage)²(pulse duration)(1000)]/(lead impedance).
VCM testing was as follows: 0% \((n = 2)\); 0–10% \((n = 14)\); 10–50% \((n = 3)\); > 50% \((n = 11)\). Two patients, both with 4965 epicardial leads, had consistent undersensing of the evoked response (Fig. 1) which prevented chronic successful VCM testing. These were the same two patients (of ages 2 and 17) who had evoked response undersensing during the initial office testing at enrolment. One additional patient (5076 active endocardial fixation) had evoked response undersensing only on the first 2 days of follow-up, while still in the acute phase post-implant, but then had accurate threshold tests for the remaining portion of the monitoring period. Chronic VCM success was 87% for epicardial leads (13/15) and 100% for endocardial leads (15/15).

Of the 28 patients with chronic VCM success, 15 (54%) had no aborted tests while 13 had occasional aborted tests (median 3 range: 1–23) typically due to high intrinsic rates. Fig. 2 shows the percentage of monitored days without aborted tests for each patient. Patients 4 and 11 had many high threshold aborted tests due to chronic evoked response undersensing and hence a very low percentage of successful measurements. Patient 29 had 47% aborted tests with up to 5 consecutive missed measurements. The remaining 27 patients had at least 80% completion rates.

Aborted tests due to detection of ventricular capture at 0 V occurred in 5 patients with a 4965 epicardial lead and in 1 patient with a 5038 VDD lead. Five of these 6 patients with zero paced aborted tests had only 1 during the follow-up period. The sixth patient had 12 during 119 days of follow-up. One of these patients also had 7 possible erroneous low chronaxie measurements. This phenomenon may be due to fusion oversensing, as all 6 patients had at least 46% ventricular sensing and 4 were observed to have fusion on ECG strips from the in-office testing. Percentages of ventricular pacing were comparable between the 6 patients with these aborted tests and the remaining 24 patients. Patients had a wide individual variability in the percentage of ventricular pacing (31 ± 36%) without any discernible difference amongst the subgroup having zero paced aborted tests. Fig. 3 shows a fusion oversense beat seen at follow-up in a 4965 patient. During the VCM testing, no clinical complications were observed.

In-office Ventricular Capture Management performance

For the group of patients completing the study, in-office VCM testing at the time of enrollment was successful in 23 (77%) patients. Four patients had high intrinsic rates preventing initial in-office VCM testing. The pacing thresholds for these patients were comparable with the remaining cohort. Three additional patients (2 epicardial, 1 endocardial) had failure during the initial VCM testing secondary to undersensing of the evoked response despite having acceptable pacing thresholds (1.37 ± 1.1 μJ).

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**Figure 1** ECG, marker, and ventricular electrogram during pacing threshold search showing evoked response undersensing. Noncapture detected up to 2.5 V when capture was occurring (arrows). LOC = loss of capture.
These three patients also had evidence of evoked response undersensing during daily at-home measurements, as described above. There were no problems of phrenic or abdominal pacing during any of the initial VCM in-office tests.

At follow-up, in-office VCM testing was successful in 26 (87%) patients with 2 having high intrinsic rates limiting applicability of this feature and 2 having failed secondary to undersensing of the evoked response (same 4965 patients as previously discussed). While success of in-office testing was highly predictive of chronic VCM success, failure of initial testing secondary to a high intrinsic rate was not predictive of later failure. Of the 4 patients with intrinsic rates precluding initial VCM testing, none had undersensing of the evoked response during the daily measurements.

Repeatability of Ventricular Capture Management testing

Amplitude thresholds were consistent over the follow-up period with a median amplitude threshold range of 0.125 V and a maximum measured threshold range of 1.125 V. The median estimated rheobase was 0.5 V (0.25–1.5 V).

Illnesses and stability of ventricular thresholds

Twenty-seven of 30 individuals were compliant with the patient diary. Eight of the 27 reported intercurrent illnesses, with 5 experiencing fever. Five were started on antibiotics, 1 on antihistamines. Pacing thresholds were not increased during episodes of illness or medication change.

Longevity savings

An additional 6.8 months (0–19 months) of projected device longevity was estimated for the 28...
patients with chronic Capture Management success using a 1.5× safety margin compared with Kappa 700 device nominals (3.5 V/1.0 ms). Longevity projections with VCM could not be made for the 2 patients with chronic evoked response undersensing because Capture Management could not calculate a recommended output (Fig. 4). There was no significant correlation between projected longevity savings and either age (p = NS, r = 0.04) or mean heart rate (p = NS, r = 0.07).

Discussion

Optimum programming of pacemaker output has always involved weighing the tradeoff of device longevity versus the need for an adequate pacing safety margin. The pacing safety margin has traditionally been set with frequent outpatient office visits determining a stimulation threshold and then reprogramming of the pacemaker as needed. This typically involves a 2:1 voltage or a 3:1 pulse duration margin to safeguard against the unpredictable development of exit block. This excessive energy delivery is often required to account for any changes in pacing thresholds that might occur as a result of changes in the tissue-electrode interface, epi/myocardial scar development following congenital heart surgery, or associated with some antiarrhythmic medication. While frequent office visits can maintain an acceptable but not excessive stimulation threshold and extend pacemaker longevity, the adoption of this policy has been reported in as few as 30% of clinical practices [15].

With the advent of evoked response capture detection, some pacemakers automatically adjust pacing output between office visits. The effectiveness is dependent upon distinguishing the ventricular evoked response from the lead polarization afterpotential. The vast majority of experience with evoked response capture detection has been with endocardial leads.

Initial studies in children and infants with AutoCapture (Pacesetter, St. Jude Medical)² and transvenous or bipolar epicardial leads have found relatively stable evoked response signals and a significant reduction in battery current drain [12,13]. However, in a recent report by Nürnberg et al. from the German Heart Institute, Berlin, in 8 patients with congenital heart disease and bipolar epicardial leads, only 3 showed preserved AutoCapture (St. Jude Medical) function in the first 6 months following implantation [16]. Unfortunately, because of certain congenital cardiovascular malformations and/or complicated vascular access, many children and young adults cannot have a transvenous ventricular lead and, further, there is often a limited amount of exposed viable myocardium to place a bipolar epicardial lead. Thus, there has been interest in ascertaining if any of the currently used capture detection devices have applicability with a single unipolar epicardial lead.

This prospective study was undertaken to determine if algorithms currently employed with Ventricular Capture Management are applicable in children and young adults, particularly those with unipolar epicardial leads. In VCM, the sense amplifier circuitry is designed to discriminate the evoked response from the lead polarization afterpotential eliminating the need for bipolar leads. In 30 children and young adults we observed successful evoked response detection in 100% of endocardial and 87% of unipolar epicardial systems. This compares favourably with the 232 adult patients enrolled in the worldwide Kappa 700 study in which successful sensing of the ventricular evoked response occurred in 96.7% of 156 patients with bipolar leads and 92.4% of 79 patients with unipolar leads [17].

Undersensing of the evoked response results in falsely detecting "noncapture" when in fact capture is occurring. If the pacemaker were programmed in "Adaptive" mode during this phenomenon, the pacemaker output would automatically be adjusted upward and there would be an increasing drain on the battery. However, in this study, chronic undersensing of the ventricular evoked response occurred in only 2 patients with an epicardial system and was also seen in the in-office

² AutoCapture, in a bipolar sensing configuration, consists of capture verification by detecting the presence of the evoked response signal within 15–62.5 ms after the pacing pulse. If capture is not detected a safety pacing pulse is delivered. Programmed pulse amplitude is adjusted to 0.3 V above the actual pacing threshold at a constant pulse duration.
testing prior to the initiation of the study. The unipolar epicardial lead (Medtronic 4965) for these 2 patients was the same as used by the other 13 patients who had both acute and chronic successful VCM testing. In addition, Capture Management offers the unique feature of providing a "Monitor Only" mode to ensure effective ventricular capture detection for a given individual before programming to "Adaptive" mode. The advantage of being able to monitor automatic capture detection prior to activating the feature was supported by Verma and colleagues who identified 10% of patients who could not have AutoCapture enabled due to suboptimal evoked response/polarization signals despite acceptable R wave and pacing thresholds [6]. In addition, because evoked response signals cannot be predicted based on clinical data [6,18] it would add an extra level of safety to use the "Monitor Only" feature before committing a patient to an "Adaptive" mode. No patient in this study who had a successful in-office assessment of VCM proved to have undersensing of the ventricular evoked response during the minimum 2-month follow-up.

In distinction from undersensing of the ventricular evoked response, inappropriate detection of capture on a ventricular test pace of zero amplitude during the pacing threshold search was identified in 5 patients with a 4965 epicardial lead and 1 patient with a 5038 VDD lead. The VCM algorithm will abort immediately when this occurs. From a clinical standpoint, the VCM testing will resume at its next regularly scheduled stimulation test and will not alter any of the current pacing properties. No identified patient variables could predict these occurrences. The exact mechanism is unknown but likely relates to fusion of a ventricular complex simultaneous with the subthreshold paced ventricular beat and may be more common in those patients with a greater amount of intrinsic ventricular sensing.

For the patient who had 7 possibly erroneous low chronaxie measurements, and never more than 2 days in a row of zero paced aborted tests, the ample safety margins would have prevented the device from setting unsafe output levels had this occurred in "Adaptive" mode. Furthermore, because the outputs are adapted downwards only one step at a time, fusion oversensing would need to occur for several days in a row with a minimum output setting below the true threshold to reduce output to the point of noncapture. Instituting a minimal 2–3 month "Monitor Only" period should be a reasonable time frame to evaluate any undersensed ventricular events as well as false chronaxie measurements that might have potentially more deleterious effects. Clinical judgment should still be applied to any patient with zero paced aborted tests during VCM testing who is pacemaker-dependent.

**Study limitations**

The present study was not an IDE study, and was intended to characterize the performance of VCM with epicardial leads, but was not intended to be used to show that the cautionary labelling against use of VCM with epicardial leads may be removed. The study is also limited by its inability to extrapolate beyond 2–3 months with regard to possible developmental changes in Ventricular Capture Management and potential late undersensing of the evoked response signal. In addition, the mean longevity is dependent on the characteristics of this particular group of patients, most notably their mean heart rate and the percentage of ventricular pacing. Because projected longevity increases were based on nominal outputs, longevity increases would have been less if actual programmed settings were lowered based on periodic threshold testing. No patients with bipolar epicardial leads completed the study, so performance of Ventricular Capture Management with bipolar epicardial leads could not be examined.

**Conclusion**

Although not an IDE study, this study showed acceptable VCM performance (in "Monitor Only" mode) in 13/15 patients with unipolar epicardial leads. An initial in-office Ventricular Capture Management test and a minimal 2-month "Monitor Only" period should identify any patient with undersensing of the ventricular evoked response who would not benefit from this feature. For children and young adults with a successful initial office visit and 2–3 month "Monitor Only" period, Ventricular Capture Management may provide substantial energy savings and extended battery life. The added battery savings over the life of the child can appreciably reduce the reoperation rate while at the same time maintain an adequate pacing safety margin.

**References**


