Automatic Atrial Threshold Measurement and Adjustment in Pediatric Patients

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Background: *Automatic threshold measurement and output adjustment are used as default settings in modern pacemakers. The purpose of the study was to assess Atrial Capture Management (ACM) of Medtronic pacemakers in pediatric patients.*

Methods: *Forty children were enrolled in two centers. Median age was 9.8 years (range 0.8–17.5 years). Half had undergone surgery for congenital heart defects; 45% of patients had an epicardial atrial lead. The pacing indication was atrioventricular block in 82% of patients and sinus node disease in 18%. Manually determined atrial thresholds and ACM measurements were compared.*

Results: *ACM measurements were within the expected variation in 37/40 (93%) of the patients. In one patient the threshold was 0.625-V lower manually than with ACM. One patient had too high an intrinsic atrial rate for ACM to be able to measure threshold. The mean threshold at 0.4 ms was 0.69 ± 0.32 V manually and 0.68 ± 0.35 V with ACM (two-tailed paired* t*-test, P = 0.52) in all patients. The mean difference was 0.012 V (95% confidence interval: −0.027, 0.053).*

The mean endocardial threshold was 0.70 ± 0.36 V manually and 0.69 ± 0.38 V with ACM; epicardial threshold was 0.67 ± 0.27 V manually and 0.68 ± 0.32 V with ACM. The difference between the measurements was 0.012 V for endocardial and 0.014 V for epicardial leads. No atrial arrhythmias due to ACM measurements were observed.

Conclusions: *ACM measures atrial thresholds reliably in pediatric patients with both endocardial and epicardial leads, allowing its use in both. Constant high intrinsic atrial rate may prevent automatic threshold measurement in young children. (PACE 2010; 33:309–313)*

atrial threshold, ACM, children, epicardial

Introduction

Atrial Capture Management (ACM) in Medtronic Enpulse™ pacemakers and subsequent models (Medtronic Inc., Minneapolis, MN, USA) was designed to automatically measure the atrial capture threshold and adjust pacing output according to the result.[1] The lowest appropriate energy should be used in order to minimize battery current drain, yet provide an adequate safety margin. A prior study on adult patients with endocardial leads[2] has shown the algorithm to be accurate and safe in adults. Therefore, the algorithm is programmed on as a default setting.

ACM performance has not been studied in children. In pediatric pacing, epicardial leads are often used because of the small size of the patient or the nature of the congenital heart disease. Epicardial pacing thresholds may be higher due to surgery-related fibrosis. Also, the sinus rate in children is much higher than in adults, and may reach or even exceed 200 beats per minute, especially during exertion. The higher heart rate may preclude successful automatic atrial threshold measurement.

ACM measures atrial pacing threshold during rest at a programmable time—usually at night. The pacemaker applies the programmable amplitude safety margin to the amplitude threshold value measured at a 0.4-ms pulse width to determine the target amplitude. If the operating amplitude is above the target, the pacemaker adapts the amplitude down toward the target. If the operating amplitude is below the target, the amplitude is immediately adapted to the target.[1] Two different methods are used for threshold measurement: the atrial chamber reset (ACR) method and the atrioventricular conduction (AVC) method. The pacemaker selects the method automatically. If the patient has

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stable sinus rhythm, the ACR method will be chosen for threshold measurements. ACR observes the absence of the next atrial sense after an atrial test pace as a marker of atrial capture. AVC method will be chosen for threshold measurements if sinus rhythm is not stable, but the patient has intact atrioventricular (AV) conduction.[2] AVC uses ventricular sense as a marker of atrial capture on a test pace. The test rate is set 15 beats per minute above the intrinsic atrial rate but is limited to 101 beats per minute, so both of these methods can be used only at heart rates below 87 beats per minute. If both methods fail, another attempt will be performed after 30 minutes. If unsuccessful, maximally three attempts with both methods can be done during 1 day. Because most pediatric pacemaker patients have an intact sinus node function, it could be assumed that ACR would be the prevalent method in this patient population. ACM cannot be utilized in patients with both sinus node disease and lack of AVC. ACM does not provide beat-to-beat capture verification.

The purpose of this prospective two-center study was to analyze the ACM performance in children with both endocardial and epicardial leads. The primary objective was to compare the in-office manual atrial capture threshold measurements with automatic ACM measurements. Secondary objectives were to compare ACM both in epicardial and endocardial leads and the applicability of the two ACM methods in children and adolescents with both normal heart structure and operated congenital heart defects.

Methods

Study Protocol

The pacemaker clinic patients and newly implanted patients with a functional atrial lead and a DDD- or DDDR-programmed dual-chamber pacemaker (Medtronic Enpulse™ or subsequent model) were enrolled in two centers in Helsinki, Finland, and Ann Arbor, MI, USA. Patients with lead integrity problems, ongoing atrial fibrillation, and high atrial output more than 5 V were excluded. The patient's age, congenital heart defect, indication for pacing, lead and device model including implant dates, and lead locations were recorded. The pacemaker was programmed to measure the atrial threshold every 24 hours and to register diagnostic ACM detail for the study. During the scheduled follow-up visit the pacemaker and threshold measurement data were stored on a disc for later analysis. Each patient was measured one to four times depending on their clinical follow-up needs, but only the first measurements were used for the analysis of equivalence between ACM and manual measurement. All measurements made during the study period were collected to assess the overall performance of ACM. The study plan was approved by the investigational review boards of both participating centers. The patients or their guardians gave a written informed consent for the study.

The difference between the manual and ACM threshold measurement at 0.4-ms pulse width were calculated. The clinical equivalence was defined as ACM being within −0.25 to +0.5 V of the manual measurement. Some circadian variation was expected because automatic measurements were performed during rest at night and manual measurements during office hours. Separate analyses were performed for patients with epicardial and endocardial leads. The overall amount of successful ACM measurements was analyzed, as well as the appropriate ACM method.

Data are presented as median with range or mean with standard deviation. Confidence intervals were calculated for differences. Two-tailed paired *t*-test was used in comparing the methods. The statistical software JMP 5.0.1a (SAS Institute, Cary, NC, USA) was used to analyze the data.

Patients

During the study period March 2006–October 2007, 40 patients, 17 girls and 23 boys, were enrolled. The median age was 9.8 years (range: 0.8–17.5 years). The atrial lead was epicardial in 18 patients (45%), whose mean age at the beginning of the study was median 6.8 years (range: 0.8–17.1 years). An endocardial atrial lead was used in 22 patients (55%); the median age of this patient group was 12.3 years (range: 5.0–17.5 years).

The endocardial atrial lead models used were Medtronic 5076 in 17 patients, Medtronic 4568 in four, Medtronic 3830 in one, and Intermedics 438–10 (Intermedics, Brussels, Belgium) in one. All endocardial leads were of active fixation type. The epicardial leads were Medtronic bipolar 4968 in 13, Medtronic unipolar 4965 in three, and Medtronic 5071 in one.

The location of the epicardial atrial leads was lateral right atrial (RA) wall in seven patients, RA appendage in five, anterior RA wall in three, and left atrium in two. The endocardial leads were placed in RA appendage in 14 patients, superior RA dome in four, lateral RA wall in two, atrial septum in two, and anterior RA wall in one patient. The leads had been implanted for median 1.2 years (range: 0.1–12.1 years). Four of the epicardial leads (43%) and eight of the endocardial leads (44%) were implanted less than 3 months prior to study enrollment.

The pacing indication was AV block in 82% of patients and sinus node disease in 18%. Half of the patients had undergone surgery for congenital

Table I.

Study Population and Pacing Indications (N = 40)

Median age (years), range	9.8	0.8–17.5
Gender (male/female)	23/17	56/44%
Atrial lead (epicardial/endocardial)	18/22	45/55%
Normal anatomy	20	
AV block/sinus node disease	18/2	
Congenital heart disease	20	
AV block/sinus node disease	15/5	

heart defects; single ventricle physiology was present in 30% of the operated patients and 15% of all patients. The indications for pacing and cardiac defects are presented in detail in Tables I and II.

Fourteen of 40 patients (35%) were on medication. Antiarrhythmic medication was used in 12 patients: sotalol in three, β-blockers in two, digoxin in six, and amiodarone in one patient. Ten patients had various diuretics; eight were on angiotensin-converting enzyme (ACE) inhibitors, one on carvedilol, and three on warfarin. There were also medications against transplant rejection and occasional antibiotics.

Results

ACM measurements were successful in 38 of 40 patients (95%) and were within the expected range in 37 of 40 patients (93%). The threshold was 0.625-V lower manually than with ACM in one patient, and another patient had too high an intrinsic atrial rate for ACM to be able to measure. Data were lost in one patient.

The mean threshold at 0.4 ms in all patients was 0.69 ± 0.32 V manually and 0.68 ± 0.35 V with ACM (two-tailed paired *t*-test P = 0.52). The mean difference was 0.012 V [95% confidence interval (CI): −0.027, 0.053 (Fig. 1)].

Table II.

Congenital Heart Defects (N = 20)

Tetralogy of Fallot	3
AV-ventriculoatrial discordance	2
Pulmonary atresia	3
Double inlet ventricle	2
Atrioventricular septal defect	3
Ventricular septal defect	2
Heart transplant	1
Dilated cardiomyopathy, atrial septal defect	2
Tricuspid atresia	1
Double outlet right ventricle	1

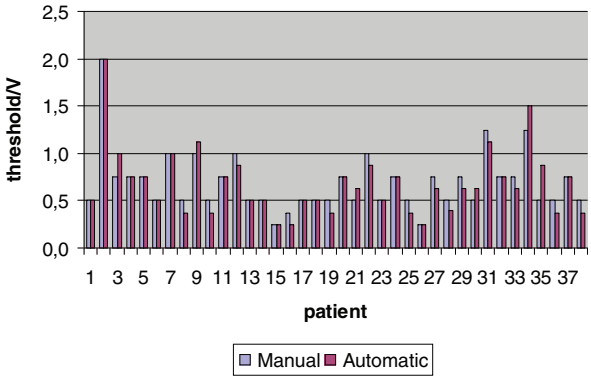

Figure 1. *Manual and automatic threshold measurements in 38 individual patients.*

The mean endocardial threshold was 0.70 ± 0.36 V manually and 0.69 ± 0.38 V with ACM; epicardial threshold was 0.67 ± 0.27 V manually and 0.68 ± 0.32 V with ACM. The difference between the measurements was 0.012 V (95% CI: −0.031, 0.056) for endocardial and 0.014 V (95% CI: −0.065, 0.094) for epicardial leads.

Successful ACM measurements within 3 days prior to follow-up were present in 37 of 40 patients (93%). Altogether 7,925 measurements were recorded. ACR method was used in 71%. The AVC method was not applicable in the 33 patients, who had AV block. No atrial arrhythmias due to ACM measurements were observed.

Discussion

This study shows that the ACM threshold measurements were equivalent with manual atrial measurements, showing that the automatic measurement is reliable in children and adolescents both with endocardial and epicardial atrial leads. Despite the lack of information on its applicability in pediatric patients, ACM function has been programmed on as a default setting in all recent Medtronic pacemakers. Based on our study, these nominal settings are safe also in children and adolescents.

In this study, there were no differences in ACM thresholds between endocardial and epicardial leads. The mean ACM threshold was 0.69 V in endocardial leads and 0.68 V in epicardial leads. The highest individual threshold was 2 V in an endocardial lead. Not only were there no differences in the thresholds but the algorithm appeared to function well for both endocardial and epicardial electrodes. Epicardial pacing is often required in children because of small size and lack of access to the atria or the ventricles, for example, in a univentricular heart. High pacing thresholds may result from fibrosis and scarring after cardiac

surgery. Cohen et al. reported that atrial thresholds remained relatively constant over 5 years in their 17-year follow-up study of epicardial leads.[3] However, ACM may provide safety against a potential threshold rise.

A successful automatic measurement was observed in 93% of our patients during the last 3 days prior to the follow-up. Seventy-one percent of 7,925 ACM measurements during the study were successful. One patient with congenital AV block and dilated cardiomyopathy had an intrinsic atrial rate of more than 100 beats per minute and no successful ACM measurements could be performed. Silvetti et al. also described three infants who did not have any successful ACM measurements. Their study group consisted of 14 patients from newborns to adults, 10 of whom had an epicardial lead.[4] Programming six ACM measurements per day, they found out that only 39% of measurements succeeded. The high atrial rates in children during daytime have probably prevented successful ACM measurements. In this study, the automatic threshold measurements were made during the night when the heart rates are lower, allowing successful ACM function. Our results show that the heart rate in children during sleep is slow enough to allow ACM measurement.

Young patients show a circadian variability of atrial threshold with higher thresholds from midnight to noon.[6] The timing of the automatic measurement at 1 a.m. or later should give the highest threshold and thus provide safety when adjusting output according to the ACM result.[3,6] Due to circadian threshold variation Biffi et al. recommended two to four daily ACM measurements. They concluded that the reliability of ACM is high over long-term follow-up.[4]

In a study designed to assess algorithm accuracy Sperzel et al. studied 200 adult pacemaker patients with ACM algorithm programmed on. The difference between manual and automatic measurement was 0.01 V and therefore clinically equivalent. There were no atrial arrhythmias in 193 patients in 892 ACM measurements during a follow-up of 1–6 months.[2] Children and adolescents following cardiac surgery for congenital heart defects can be prone to atrial arrhythmias. ACM measurements did not provoke atrial arrhythmias in our patients. We did not perform Holter monitoring, but atrial arrhythmias are recognized by the pacemaker and would have been detected in the pacemaker diagnostic memory at interrogation.

The ACR method was used in the majority of patients as expected. The vast majority of our patients had normal sinus node function and atrial pacing was seldom needed. Only seven patients (18%), two with normal anatomy and five with operated congenital heart defect, needed atrial pacing with rate response mode because of sinus node dysfunction. This finding reflects the fact that the indication for pacing in children and adolescents is mainly congenital or postoperative AV block.

We did not have any patients with high atrial thresholds, which could have prevented accurate ACM measurements. Children with both sinus node and AV node disease may prove to be problematic for ACM as neither ACR or AVC can be used if both chambers are 100% paced because of the measurement method restrictions.[5] Also, marked sinus arrhythmia, often present in children, can preclude the use of ACR. The problem in one of our patients was constant high intrinsic atrial rate. Both ACR and AVC methods can operate only below heart rate of 87 beats per minute, which can be a disadvantage in young patients. Some of the patients had a programmed lower rate of 80 beats per minute, which may also cause difficulties in performing ACM threshold test.

Besides providing safety against acute threshold rises, the goal of automatic threshold measurements and output adjustments is to increase pacemaker generator longevity.[6] Patients who need constant atrial pacing would benefit most in this respect. However, these patients are a minority in children and adolescents. An added benefit in this era of enhanced remote monitoring is the ability for clinicians to see threshold trends over time to monitor overall lead performance.

Limitations

The current study was not intended to evaluate the accuracy of the ACM algorithm. The study and results described by Sperzel et al. provide algorithm accuracy.[2]

The two ACM methods provide the ability to measure atrial thresholds in the case of normal AVC as well as consistent atrial sinus rhythm. If both of these conditions are absent (e.g., AV block and sinus node disease) then ACM will not be able to measure a threshold. Also, constant high intrinsic atrial rate, above 87 beats per minute, may prevent automatic threshold measurement in young children. A third limitation of ACM is that it cannot measure thresholds higher than 2.5 V. With these limitations, ACM cannot be recommended in children and young patients who have high-atrial thresholds above 2.5 V, need for pacing both chambers, marked sinus arrhythmia, or a programmed lower rate above 80 beats per minute.

Conclusion

ACM of Medtronic pacemakers measures atrial thresholds reliably in select pediatric

patients with both endocardial and epicardial leads allowing its use in both. Constant high intrinsic atrial rate may prevent automatic threshold measurement in young children.

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