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Cardiac Electrophysiology

Advances for Treating In-Hospital Cardiac Arrest: Safety and Effectiveness of a New Automatic External Cardioverter-Defibrillator

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OBJECTIVES The purpose of this study was to prospectively analyze the performance and safety of a new programmable, fully automatic external cardioverter-defibrillator (AECD) in a European multicenter trial.

BACKGROUND Although, the response time to cardiac arrest (CA) is a major determinant of mortality and morbidity, in-hospital strategies have not significantly changed during the last 30 years.

METHODS Patients (n = 117) at risk of CA in monitored wards (n = 51) and patients undergoing electrophysiologic testing or implantable cardioverter-defibrillator (ICD) implantation (n = 66) were enrolled. The accuracy of the automatic response of the device to any change of rhythm (lasting >1 s and >4 beats) was confirmed by reviewing the simultaneously recorded Holter data and the programmed parameters.

RESULTS During 1,240 h, 1,988 episodes of rhythm changes were documented. A total of 115 episodes lasted ≥10 s or needed treatment (pacing, n = 32; ICD, n = 51; AECD, n = 35) for termination. The device detected ventricular tachyarrhythmias with a sensitivity of 100% and specificity of 97.6% (true negatives, n = 1,454; true positives, n = 499; false positives, n = 35; false negatives, n = 0). The false positives were all caused by T-wave oversensing during ventricular pacing. There were no complications or adverse events. The mean response time was 14.4 s for those episodes needing a full charge of the capacitor.

CONCLUSIONS This new AECD is safe and effective in detecting, monitoring, and treating spontaneous arrhythmias. This fully automatic device shortens the response time to treatment, and it is likely that it will significantly improve the outcome of patients with in-hospital CA. (J Am Coll Cardiol 2003;41:627–32) © 2003 by the American College of Cardiology Foundation

Time to defibrillation is the single most important determinant of survival in cardiac arrest (CA) (1–15) as a result of several factors: 1) the most frequent rhythm at the start of resuscitation maneuvers is ventricular fibrillation (VF); 2) the most effective treatment for VF or ventricular tachycardia (VT) is usually electrical defibrillation; 3) the probability of successful defibrillation diminishes rapidly over time (4,10,14); and 4) VF tends to evolve to asystole within a few minutes (1–3,5,6,10,11,16). Survival rates after VF decrease approximately 7% to 10% with every minute that defibrillation is delayed (1–3,5,6). Furthermore, the cerebral cortex is irreversibly damaged if circulation is not quickly resumed (1,5,8,9,13,16,17).

Although ample evidence exists supporting the need for rapid defibrillation, and important advances in out-of-hospital CA treatment have been achieved (e.g., out-of-hospital CA quick response programs) (1–3,6–12,14,18), in-hospital CA is still a major problem without major advances (e.g., changing strategies) during the last 30 years, which has led to significant mortality and morbidity (8,13,19,20). Therefore, the aim of the present study was to prospectively analyze the performance and safety of a full in-hospital automatic external cardioverter-defibrillator (AECD).

PATIENTS AND METHODS

Patients. Patients (n = 117; 18 years of age or older) at risk of sustained VT or VF in the intensive care unit, coronary care unit, or emergency room (n = 51) and patients undergoing electrophysiologic testing (because of docu-

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Abbreviations and Acronyms

AECD = automatic external cardioverter-defibrillator
CA = cardiac arrest
ECG = electrocardiograph/electrocardiographic
ICD = implantable cardioverter-defibrillator
VF = ventricular fibrillation
VT = ventricular tachycardia

mented or suspected VT/VF) or implantation of implantable cardioverter-defibrillators (ICD) (n = 66) were included in this prospective, multicenter European study. From the 117 patients, 2 patients were studied under both invasive and noninvasive conditions. Thus, all patients enrolled were in a monitored setting. Patients with previously implanted and activated cardioverter-defibrillators or pacemakers were excluded. Atrial fibrillation was not considered as an exclusion criterion.

Methods. In addition to the standards of care of each institution, patients underwent monitoring of their cardiac rhythm by the new AECD (Powerheart, Cardiac Science Inc., Irvine, California) using self-adhesive electrodes. Each AECD provided an analog output electrocardiographic (ECG) signal, which was recorded by conventional Holter system for off-line review and confirmation of the patients' rhythms.

The programmed detection rates of tachyarrhythmias, therapy, as well as the duration and placement of leads (e.g., sternal-apex or anterior-posterior) for monitoring were at the discretion of the treating physicians based on the individual characteristics of patients. During ICD implantations, the AECD was used as a "rescue" defibrillator. Pacing is considered a contraindication for AECD use but was used in the study for investigational purposes only. Enrollment of participating clinical centers and patients did comply with the requirements of the individual clinical institutions (e.g., Ethical Committee), including informed written consent of patients.

All adverse events or unanticipated adverse device events relating to the rights, safety, or welfare of patients had to be reported.

Device description. The AECD is designed to continuously monitor, analyze, and classify the ECG rhythm of patients. Upon detection of a ventricular tachyarrhythmia, the AECD can provide treatment by automatically delivering cardioversion and/or defibrillation energy in seconds, when needed (automatic mode). Should the arrhythmia persist, the AECD can proceed with a subsequent delivery of energy (up to 9 shocks per episode) after each additional evaluation and charging period. The energy and delay of each shock can be programmed. Shock delivery is noncommitted such that if the rhythm spontaneously converts, therapy will be automatically aborted.

The AECD can also operate in advisory mode, whereby the device charges the capacitor when a ventricular tachyarrhythmia is detected and prompts the operator to press the paired shock delivery buttons. When the device works in advisory mode, it automatically discharges internally if a shock has not been delivered within 1 min.

The AECD has a third mode of operation: the manual mode. This allows the operator to select the energy, charge the capacitor, and deliver the therapy when needed. The manual mode was not evaluated in this study.

Tachyarrhythmias were detected primarily using a programmable rate criterion. Furthermore, for better discrimination of supraventricular versus ventricular rhythms, a modulation domain function, which combines frequency and amplitude content of the signal (21), was available at the physician's discretion. Each time a ventricular tachyarrhythmia is detected, the device immediately and automatically prints an ECG of the episode. Furthermore, episodes lasting longer than 10 s are internally stored and may be transferred to any conventional personal computer for documentation. A delay (10 to 600 s) between arrhythmia recognition and shock delivery can be programmed by the operator. This AECD has been approved by the Food and Drug Administration as well as by the European Community Administration.

Data analysis. Demographic, programmed parameters and evaluation data (including ECG strips and Holter tapes) were entered into a database for analysis. As the Holter tapes were used to evaluate the patient outcomes, the Holter recordings were classified into episodes. They were determined from the time a rhythm change (e.g., supraventricular vs. ventricular) was established until the end of the rhythm change or when therapy was delivered, whichever occurred first. Only rhythms persisting more than 1 s and lasting more than 4 beats were considered as an episode. Because every change of rhythm constituted a new challenge for the AECD, the response of the device to all episodes was evaluated. Thus, each episode documented with the Holter tapes was analyzed and classified as true positive, true negative, false positive, or false negative on the basis of the programmed parameters and the device response to the tachyarrhythmia (review of stored data and all ECG strips). Sensitivity was calculated as true positives divided by the sum of true positives and false negatives. Specificity was calculated as true negatives divided by the sum of true negatives and false positives.

The response time was evaluated in those episodes leading to a full charge of the capacitor. It was defined as the sum of the arrhythmia recognition period and the charging period. As mentioned in the previous text, the minimum programmable arrhythmia-to-shock delay was 10 s. For those episodes in which a prolonged arrhythmia-to-shock delay had been programmed (e.g., 30 s), the response time included only the recognition and charging time and was considered 10 s if that sum had been shorter.

Continuous data are presented as mean ± SD.

RESULTS

A total of 117 patients were included in the study: 51 patients (44%) in monitoring wards (emergency room, intensive care unit, or coronary care unit) and 66 patients (56%) during electrophysiologic studies or ICD implantations. From the overall cohort, two patients were studied under both invasive and noninvasive conditions. The mean age was 62 ± 16 years; 25 patients were female (21.4%). Cardiac diagnoses included coronary artery disease (n = 72 [61.5%]), dilated cardiomyopathy (n = 11 [9.4%]), hypertrophic cardiomyopathy (n = 6 [5.1%]), valvular heart disease (n = 5 [4.3%]), and others (n = 23 [19.7%]). Eleven patients (9.4%) presented with persistent atrial fibrillation, whereas 106 patients (90.6%) presented in sinus rhythm.

A total of 125 and 1,115 h of monitoring were performed during invasive procedures and at the ward, respectively. During the combined monitoring (1,240 h), a total of 1,988 episodes of change of rhythm occurred. A total of 115 episodes (5.8%; ventricular origin, n = 84; spontaneous, n = 38) lasted ≥10 s or needed electrical treatment for termination. During invasive procedures, a total of 34, 5, and 16 episodes (≥10 s) of monomorphic or polymorphic VT and VF were documented, respectively. In monitoring wards, 10, 2, and 17 episodes of those arrhythmias occurred, respectively.

The mean programmed ventricular arrhythmia detection rate was 166 ± 13 beats/min. There were no significant differences of programmed parameters at the ward compared with during invasive procedures. The modulation domain function was used by the investigators in 74 patients (63%) (ward, n = 28; invasive procedures, n = 46; mean programmed rate 185 ± 9 beats/min). According to the programmed parameters, there were 1,454 true negatives, 499 true positives, 35 false positives, and no false negatives. Thus, sensitivity was 100% and specificity was 97.6% (97.3% for invasive procedures; 99.2% for monitoring at the ward). False positives resulted from T-wave oversensing during ventricular pacing in five patients (Fig. 1). Because the device was in advisory mode during invasive procedures and pacing, inappropriate therapy never occurred. During movement artifacts in three patients, the device alarmed on five occasions but the episode was classified correctly within 2 to 4 s by the AECD. During monitoring, patients had no restrictions on movement beyond those normally incurred in their course of treatment. The response time was 14 ± 4 s.

Spontaneous or induced non-sustained and sustained monomorphic or polymorphic VT as well as VF were always correctly detected and classified (sensitivity of 100%). In addition, all those episodes (n = 35), which were treated by the device (invasive procedures, n = 12; ward, n = 23) were successfully (100% efficacy) converted to normal rhythms (Fig. 1) (first shock success 94.3%). Those 23 AECD interventions in the ward were for VF episodes (n = 15), monomorphic VT (n = 6), polymorphic VT (n = 1), and hemodynamically intolerable atrial flutter (n = 1). All AECD shocks during invasive procedures were given because of hemodynamically not tolerable VT or VF, which could not be interrupted by pacing or with the ICD that should be implanted.

Furthermore, during ICD implantation, a detection delay (mean 6.1 s, range 0 to 8 s) was observed in the recognition of the induced VF when T-wave shock or 50-Hz current with the ICD was used for arrhythmia induction. This delay was caused by saturation of the front end stage of the device.

There were no complications or adverse events.

DISCUSSION

The main findings of this study are that the AECD is safe and highly effective in monitoring, detecting, and treating spontaneous rhythms. The use of the device shortens the response time to CA to a mean of <15 s. Therefore, a significant improvement in the treatment of in-hospital CA should be expected with its wide use. Furthermore, extending the capabilities of monitoring units (intensive care unit, coronary care unit, and emergency room) to non-monitored wards is feasible and could lead to allocation of human resources to critical areas for patients needing closer medical attention.

Previous studies. Only one clinical study has evaluated this technology (21). Although some differences exist (e.g., sample size, hours of monitoring, definition of episodes, software version), the present study reaffirms the initial clinical experience in the U.S. trial with the device (21) in which the authors reported a sensitivity of 100% and a specificity of 98.8%. Both studies led to the same conclusions (e.g., the highly effective performance and safety of the device). The present study shows a shorter response time (<15 s) than that reported by the American investigators (22 s) as a result of technological (e.g., software) improvement.

Effects of time to shock. Ischemia risk and defibrillation thresholds increase with arrhythmia duration (4). Therefore, early intervention (arrhythmia interruption) is mandatory and clearly improves outcome (1–6,9,13,16,19,22). In addition, more than two decades of experience with electrophysiologic testing (including induction of fast VT and VF) and worldwide testing and implantation of several thousand ICDs have provided evidence that "early" arrhythmia interruption has virtually a 100% clinical efficacy without secondary neurologic damage. These data stress the usefulness and safety of immediate interruption of even lethal arrhythmias.

In-hospital CA. Sustained VT and VF even in hospitalized patients are major causes of morbidity and mortality (8,13,15,19,20). Although survival to hospital discharge offers an objective evaluation point and is used in the broad majority of reports, several patients who survive a CA present neurologic damage, which is highly dependent on the response time to CA (1,5,8,9,13,16,17). Therefore, the

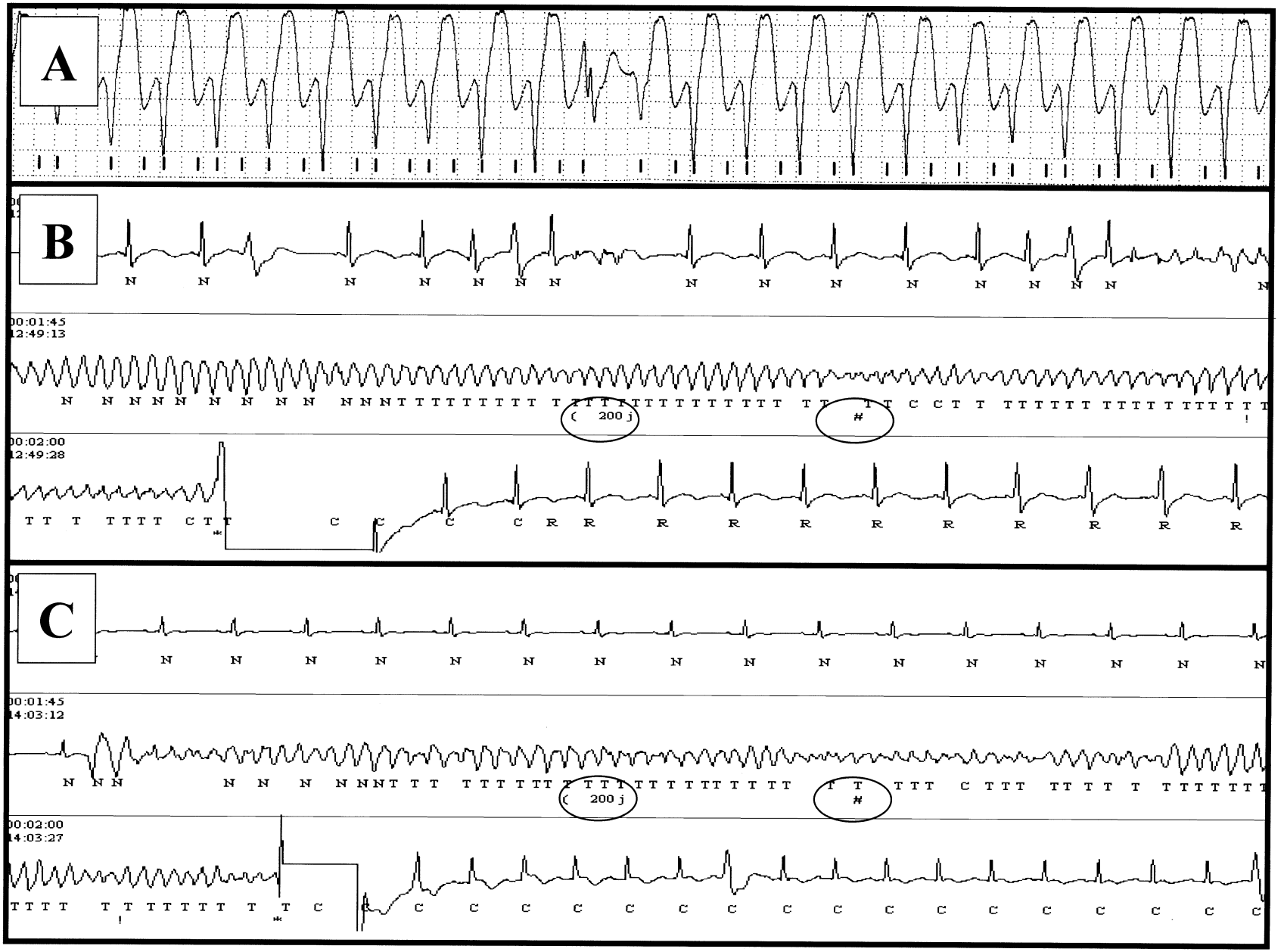

Figure 1. **(A)** T-wave oversensing may be observed during ventricular pacing as indicated by the markers. **(B and C)** Recordings of the AECD response to two episodes of spontaneous VF in two different patients. The **first circle** indicates the beginning of charge (200 J) of the device; the **second circle** indicates the full charge of the automatic external cardioverter defibrillator, which was in advisory mode.

neurologic status should also be considered when reporting results of resuscitation procedures (13,18).

The absence of in-hospital early defibrillation programs is evident in the scarcity of data related to deployment of AECDs in hospitals and its impact on patient outcome (13,15,20). Continuous ECG monitoring allows identification of such arrhythmias, and alarm systems alert nursing and medical staff. However, a time delay between the arrhythmic event and human intervention obviously exists (recognition of the arrhythmia by the ECG monitoring system; alarming process; reaction of personnel such as interpretation of rhythm and response to the arrhythmia, including transport of necessary equipment). Furthermore, although difficult to accept, this time delay may be prolonged in certain circumstances, even in monitoring wards. In addition, response time intervals for in-hospital resuscitation events are often inaccurate and must be corrected before documented times to defibrillation can be considered reliable (18).

As stated in major guidelines, early defibrillation is a high-priority goal in both out-of-hospital and in-hospital CA (18,23–25). Clearly, the earlier defibrillation occurs, the better the prognosis (1,2,5,6,10–12,14,16). The capability to provide early defibrillation within patient-care areas should be considered as an obligation of the modern hospital, which is possible with the evaluated technology.

It is well known that several episodes of CA often occur outside monitored areas. Recently, Herlitz et al. (15) reported that out of 557 patients suffering in-hospital CA, only 292 patients (53%) were in monitored wards, and from those only 43.2% of the patients could be discharged alive. They reported that the median interval between collapse and first defibrillation was 1 min in monitored wards and 5 min in non-monitored wards. Only 31% of patients from non-monitored wards could be discharged alive, and with a cerebral performance inferior to that of survivors of monitored wards. Other authors (20) present similar data showing better in-hospital survival for witnessed arrest (25%) than for non-witnessed arrest (7%) but, in addition, they report a disproportionately high incidence of non-witnessed arrests during the night (12 AM to 6 AM), resulting in a very poor survival rate (0%).

Future perspectives. This prospective, multicenter European trial suggests that in-hospital CA morbidity and mortality could be reduced by a safe and highly effective, new, fully AECD. In addition, the device could save resources of critical areas (e.g., coronary care unit) for patients needing closer medical support by extending the capabilities of traditional monitored wards to other areas of the hospital with a higher patient/nurse ratio. Examples include patients admitted with an acute myocardial infarction (carrying a risk of primary VF), patients waiting for ICD implantation, or patients waiting for transplantation who do not present a severe, acute hemodynamic compromise. Furthermore, CA mortality in non-monitored wards is very high (15,20), reflecting a lack of human resources and the inadequacy of our risk stratification strategies. Thus, very rapid intervention with the technology described in this study could reduce morbidity and mortality associated with CA (e.g., neurologic damage). These are goals of any modern hospital and should be a new standard of care.

Study limitations. The study evaluated the response of the AECD to both spontaneous and induced arrhythmias. T-wave oversensing during ventricular pacing (rarely) and an arrhythmia detection delay (mean 6.1 s) after T-wave shock or using 50 Hz during ICD implantations were observed independent of the quality of the sensed signal during the spontaneous rhythm. The device is designed for the detection and treatment of spontaneous ventricular tachyarrhythmias. Pacing, T-wave shock, or 50-Hz current were only used in the study for investigational purposes.

CONCLUSIONS

Early automatic defibrillation of in-hospital CA is now feasible with a device which is fast (response time <15 s), safe (no complications occurred), and effective for detecting and classifying arrhythmias (sensitivity 100%, specificity 97.6%) as well as for treating those events that required counter-shock therapy (100% efficacy). It is likely that the use of this device will significantly improve the outcome of patients with in-hospital CA.

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APPENDIX

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