# Is New Era Dawning for In-Hospital Cardiac Arrest?

## *Bedside monitors that detect arrythmias and deliver shocks make "code blues" obsolete, cardiologist says.*

BY BRUCE JANCIN
*Denver Bureau*

VANCOUVER, B.C. — The traditional "code blue" strategy of handling in-hospital cardiac arrests has remained essentially unchanged for 30 years, a period during which—in sharp contrast—massive resources have been devoted to improving public access defibrillation for out-of-hospital cardiac arrest, Antoni Martinez-Rubio, M.D., said at a meeting of the International Academy of Cardiology."We [cardiologists] have spent lots of money and done lots of reports looking at what happens outside our hospitals, but we have not looked hard enough at what happens inside our hospitals," according to Dr. Martinez-Rubio, a cardiologist at Sabadell Hospital, Barcelona.

Nearly a third (30%) of all sudden cardiac deaths occur in-hospital. The literature indicates that the acute survival rate following attempted resuscitation of in-hospital cardiac arrest is 40%-45%. Only 15%-20% of patients are discharged alive, many with permanent neurologic impairment.

Given the inefficiencies and generally poor outcomes of the code blue approach, it's time for a major change in how in-hospital cardiac arrests are managed. And the necessary tool is already at hand in the form of the Food and Drug Administration–approved Powerheart Cardiac Rhythm Module (CRM), he added.

The CRM continuously monitors a patient's heart at the bedside, detects onset of a life-threatening arrhythmia, and automatically delivers a shock for external cardioversion. In the multicenter European trial headed by Dr. Martinez-Rubio and sponsored by Cardiac Science Inc., the mean lapsed time between arrhythmia onset and delivery of a defibrillatory shock was 15 seconds.

Contrast that to the traditional code blue scenario, in which a patient is monitored by telemetry in a high-cost ICU or coronary care unit. In that setting a detected arrhythmia triggers an alarm, which has to be recognized by the nursing staff, which then calls for the crash cart and physicians to come to the bedside. All of this takes time. And as a recent American Heart Association report emphasized, the earlier cardiac resuscitation can be performed, the better. Indeed, survival rates decrease by 7%-10% for every minute defibrillation is delayed, the cardiologist continued.

In addition to the 117-patient European multicenter study led by Dr. Martinez-Rubio (J. Am. Coll. Cardiol. 2003;41:627-32) there has also been a favorable single-center Brazilian study of the CRM (Resuscitation 2004;63:11-6). In addition, physicians at Maimonides Medical Center in Brooklyn, N.Y., reported that the response time to simulated cardiac arrest in their ICU and CCU averaged nearly 3 minutes, compared with just 38 seconds for the CRM to charge up and deliver a shock (Resuscitation 2004;63:183-8).

"In my opinion, this should be the new standard of care," Dr. Martinez-Rubio declared. He provided an update on an ongoing study he is directing in which patients at risk for arrhythmic death are being randomized to traditional monitoring and code blue response in the CCU or to a stay in a regular hospital ward while connected to the Powerheart.

With 95 patients randomized to date, during 5,340 hours of monitoring outside the CCU there have been 122 arrhythmic events, including 36 cases of ventricular arrhythmia. There are as yet no significant differences in clinical outcome; however, the cost savings achieved by using the CRM on a regular ward instead of traditional monitoring in the CCU amounts thus far to $89,000. Moreover, that is assuming a $400 per day difference in the cost of staying in a regular ward, compared with the CCU, which is probably a considerable underestimate.

In addition, an ongoing prospective study at the University of Michigan, Ann Arbor, is comparing the effectiveness of the traditional code blue emergency response protocol with the CRM in patients in the university hospital's cardiac ICU. The study is being led by Kim A. Eagle, M.D., clinical director of the university's cardiovascular center. ■

# New Studies Challenge CMS Coverage Restriction for ICDs

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NEW ORLEANS — Medicare's policy of covering implantable cardioverter defibrillator therapy in patients with nonischemic dilated cardiomyopathy with a disease duration of at least 9 months was undercut by two studies presented at the annual meeting of the Heart Rhythm Society.

The studies by two separate teams of investigators independently showed that the risk of sudden cardiac death—and the benefit from implantable cardioverter defibrillator (ICD) therapy—was the same whether patients met the 9-month criterion or not.

The patients with nonischemic dilated cardiomyopathy who met Centers for Medicare and Medicaid Services (CMS) criteria for ICD implantation, except that their disease had been diagnosed less than 9 months earlier, had benefits similar to those seen in patients whose condition had been diagnosed at least 9 months earlier and who therefore were eligible for ICD coverage. The benefit was also seen in patients whose nonischemic dilated cardiomyopathy (NIDCM) was diagnosed less than 3 months earlier.

"These results suggest that any delay in ICD implantation will reduce survival benefit. Therefore, if ICD therapy is selected for a patient with nonischemic cardiomyopathy . . . then the ICD should be implanted without delay," said Kelley P. Anderson, M.D., of the Marshfield (Wisc.) Clinic.

In January, CMS expanded coverage for ICD therapy beyond patients with ischemic cardiomyopathy for the first time to include selected individuals with NIDCM. But to be eligible, patients had to have New York Heart Association class III or worse heart failure, a left ventricular ejection fraction of 35% or less, and—the focus of controversy—they had to have nonischemic dilated cardiomyopathy of more than 9 months' duration.

Patients who had been diagnosed 3-9 months earlier would be eligible for reimbursement but only if they were entered in a special registry, the details of which the Heart Rhythm Society and CMS are still hammering out.

Patients with nonischemic dilated cardiomyopathy of less than 3 months' duration are ineligible for ICD coverage because CMS has deemed there is a lack of clinical evidence of benefit.

Dr. Anderson presented a new retrospective post hoc analysis of data from the prospective Defibrillators in Nonischemic Cardiomyopathy Treatment Evaluation (DEFINITE) trial, in which 458 patients with NIDCM were randomized to optimal medical therapy for heart failure with or without an ICD, regardless of the duration of NIDCM.

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At 2.5 years of follow-up, survival in the 150 patients with nonischemic dilated cardiomyopathy of not more than 3 months' duration at randomization was 89.9%, after the investigators controlled for treatment assignment. This wasn't significantly different from the 84.0% rate in patients with NIDCM of greater than 3 months' duration. Similarly, survival in the 216 patients with NIDCM of 9 months' duration or less was comparable to that of patients with greater than 9 months' duration.

Moreover, among the subgroup of patients with nonischemic dilated cardiomyopathy of 3 months' duration or less at the time of randomization, those assigned to receive an ICD were 63% more likely to be alive at 2.5 years than were those randomized to optimal medical management. Similarly, those whose NIDCM had been diagnosed 9 months or less prior to ICD implantation were 52% more likely to survive to 2.5 years than were comparable patients randomized to medical therapy, he continued.

Late-breaker session cochair David S. Cannom, M.D., called the new DEFINITE data "very provocative," adding, however, that he found troubling what he termed the "startlingly high" early arrhythmic event rate in the study population.

"The argument might be that you've picked a particularly vulnerable population that's suffering from an acute syndrome of some type—say, a viral etiology—that would get better over a short period of time anyway without an ICD," said Dr. Cannom, director of cardiology at Good Samaritan Hospital, Los Angeles, and a past president of the Heart Rhythm Society.

His cochair, Sanjeev Saksena, M.D., commented that he'd be very interested to see serial ejection fraction data for the DEFINITE participants. A significant improvement over time would suggest Dr. Cannom's hunch is correct.

"We are often pressured to intervene to put in an ICD in these patients with nonischemic cardiomyopathy [of short duration], and then 3 or 4 weeks later the ejection fraction has improved," said Dr. Saksena, professor of medicine at Robert Wood Johnson Medical School in New Brunswick, N.J.

Dr. Anderson replied that the investigators attempted to exclude from DEFINITE any patients with myocarditis or other reversible causes of NIDCM, although that can be difficult. He added that the ejection fraction data are still being processed. But even if it turns out many of these patients have a self-limited, reversible cardiomyopathy, the challenge will be to protect them from arrhythmic death during those initial months of high vulnerability.

"Maybe one should use a home external defibrillator, or a life vest, or maybe after a period of time explant an ICD," he said.

In a separate presentation, Kevin J. Makati, M.D., presented a retrospective study involving 131 patients with NIDCM treated at Tufts-New England Medical Center, Boston.

Of the 131 patients, 79 had been diagnosed with the disorder at least 9 months and a mean of 66 months prior to ICD implantation. The remaining 52 had carried the diagnosis of NIDCM for less than 9 and a mean of 1.4 months at the time of implantation.

During 27 months of follow-up, there were no differences between the two patient groups in terms of the occurrence of ventricular arrhythmias or life-threatening ventricular arrhythmias.

"This study shows a clear benefit of ICDs for patients with cardiomyopathy, irrespective of when they were diagnosed," commented Stephen C. Hammill, M.D., immediate past president of the Heart Rhythm Society. "CMS may want to revisit the coverage criteria for these patients in light of these findings."

Dr. Anderson and Dr. Makati declared no conflicts of interest. ■