Treatment To Prevent Sudden Cardiac Death

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Key Finding: The most effective antiarrhythmic medication is amiodarone, which lowers sudden cardiac deaths by 13-19 percent. Implantable cardiac defibrillators, when combined with alternative therapy (usually amiodarone), reduced deaths by 24 percent.

The study, the Cardiac Arrhythmia Patient Outcomes Research Team, was conducted at Stanford University. It was funded by the Agency for Healthcare Research and Quality (AHRQ), the Federal Government's lead agency charged with supporting research to improve the quality of health care, reduce its cost, address patient safety and medical errors, and broaden access to essential services.

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Introduction

A quarter of all deaths in the United States—about a thousand deaths a day—are sudden cardiac deaths, which are unexpected and occur within an hour of the time that symptoms first appear. Sudden cardiac deaths, in turn, are often linked to ventricular arrhythmia. It is extremely important to identify patients at risk for sudden (as opposed to nonsudden) cardiac death with a high degree of sensitivity and specificity. It is also important to identify the treatments most apt to save lives and increase quality of life.

In 1994, the Agency for Healthcare Research and Quality (AHRQ) funded a Patient Outcomes Research Team (PORT) on cardiac arrhythmias. The PORT addressed major questions concerning the value of screening and efficacy of treatments—specifically, drug treatments and implantable cardiac defibrillators, or ICDs. (An ICD is surgically implanted in a patient's chest to monitor the heart's rhythm and disrupt potentially serious arrhythmias with an electric shock.)

In September 2002, the *American Heart Journal* published seven studies from the Cardiac Arrhythmia PORT. Overall, the studies demonstrate that the increasing use of ICDs for managing ventricular arrhythmias has reduced mortality and also may have improved patients' quality of life. Nevertheless, considerable variation exists in the use of ICDs, suggesting that doctors are uncertain as to when they should be used or that such decisions are being driven by nonclinical factors. The challenge of identifying which patients are best suited for ICD implantation remains. This *Clinical Highlights* summarizes the studies.

Methods

Principal Investigator Mark Hlatky, M.D., led the Cardiac Arrhythmia PORT in interrelated projects using a variety of methods that depended on the topic of interest. Methods ranged from analysis of administrative data, to conducting a case-control study, to synthesis of relevant literature, to construction of a decision model for screening and treating patients at risk for sudden cardiac death.

Summary of Findings

Good treatments are available for people at risk for sudden cardiac death.

Drug treatment for sudden cardiac death has improved over the years. Deaths from sudden cardiac death can be lowered by preventing the specific heart rhythm disturbances (ventricular arrhythmias) associated with it. The type I antiarrhythmic drugs (sodium channel blockers) often used in the past are no longer considered helpful. In fact, in one study, they were associated with a 21-percent increase in death rates among people at risk for sudden cardiac death. However, some type III antiarrhythmic drugs (potassium channel blockers), including amiodarone and sotalol, are effective. In a systematic review of methods of preventing sudden cardiac death, amiodarone was identified as the most effective medication, decreasing mortality by 13 to 19 percent compared to a placebo.

Implantable cardiac defibrillators are effective and their use has expanded markedly. Surgically implanting an ICD to monitor and correct the heart rate can offer additional help. In the same review of treatments to prevent sudden cardiac death, researchers found that when ICDs were combined with other therapy (most often amiodarone), the ICDs reduced mortality by an additional 24 percent. ICDs appeared to be most effective for patients who had an episode of sustained ventricular tachycardia or ventricular fibrillation. The evidence is less strong for patients who had an earlier myocardial infarction and a low ejection fraction.

In another study, researchers examined Medicare data for the period 1987-95 and California hospital discharge data for 1991-95 to study trends in the use and outcomes of ICDs. During the study period, ICD use increased more than tenfold. Mortality rates fell from 6.0 percent to 1.9 percent for the first 30 days after device implantation and from 19.3 percent to 11.4 percent for the year following implantation. It could not be determined whether these better outcomes were the result of improved effectiveness of the device or improved patient selection. Over the study period, the need for device revision or replacement and overall costs remained stable.

In another study, it was found that ICD patients had higher overall costs than patients treated only with medication because of the upfront costs of the device, but their followup costs were lower.

Quality of life for these patients may be improving. ICDs and antiarrhythmic medications to prevent sudden cardiac death are effective in reducing deaths, but their impact on quality of life (QOL) is less clear. In a study that followed 264 patients with new cases of life-threatening ventricular arrhythmias, QOL decreased at first but gradually improved with time. The overall improvements in QOL were greater for patients with ICDs than for patients treated only with amiodarone. These findings, which contrast with previous research, may reflect advances in ICD technology and differences in study populations.

Identifying patients who will benefit from these treatments is difficult.

Patients at high risk of sudden cardiac death are hard to identify. Targeting the patients who can benefit from these specific therapies aimed at cardiac arrhythmias is difficult. Researchers evaluated the possibility of

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distinguishing patients at risk for sudden vs. nonsudden death using clinical characteristics (obtained from administrative data and chart reviews). Unfortunately, they were not able to identify significant differences between the two groups. They concluded that standard clinical evaluation is much better at predicting the overall risk of death than at predicting whether it will be sudden or nonsudden.

Accurate targeting is necessary for cost-effective treatment. Selection of the most appropriate patients to get ICDs is complex. Researchers used a statistical model incorporating mortality rates (for sudden and nonsudden cardiac deaths and for noncardiac deaths) and costs for ICD treatment and for amiodarone treatment in order to evaluate cost-effectiveness. The cost-effectiveness of ICD implantation varied markedly, depending on the total cardiac mortality rate and the ratio of sudden cardiac death to nonsudden cardiac death. However, ICDs always cost at least approximately $30,000 for each quality-adjusted year of life. Stategies for risk stratification need to distinguish patients who die suddenly from those who die nonsuddenly, not just to distinguish patients who die suddenly from those who live.

Trends are encouraging but problems remain.

More testing and better treatment improve outcomes. A study of hospital treatment for Medicare patients with ventricular arrhythmias looked at trends in the 1980s and 1990s. Most patients who arrive in the hospital for a ventricular arrhythmia are declared dead in the emergency department. But for those who survive and are admitted to the hospital, electrophysiologic

testing to identify the risk of sudden death rose from 3 percent in 1987 to 22 percent in 1995 and the use of ICDs rose from 1 percent to 13 percent. Survival increased by half a percentage point a year during the study period and hospitalization costs increased 8 percent each year. The improvements in mortality seen in this observational study are similar to those seen in randomized trials.

Treatment disparities between groups remain. A study examined whether there were racial/ethnic disparities in terms of care and outcomes for patients with ventricular arrhythmias admitted to California hospitals from 1992 to 1994. Analyzing discharge abstracts, investigators found that blacks were significantly less likely than whites to have electrophysiologic studies or to get an ICD. Blacks had 18 percent higher mortality rates than whites, even after controlling for multiple confounding risk factors. These findings are consistent with studies of other cardiovascular procedures. Disparities were also found for factors other than race/ethnicity, including age, sex, and insurance status.

For More Information

The studies summarized here appeared in the September 2002 issue of the *American Heart Journal*, Volume 144. They are:

Risk of sudden versus nonsudden cardiac death in patients with coronary artery disease (Every N, Hallstrom A, McDonald KM, et al.)

Utilization and outcomes of the implantable cardioverter defibrillator, 1987 to 1995 (Hlatky MA, Saynina O, McDonald KM, et al.)

Life after a ventricular arrhythmia (Hsu J, Uratsu C, Truman A, et al.)

Trends in hospital treatment of ventricular arrhythmias among Medicare beneficiaries, 1985 to 1995 (McDonald KM, Hlatky MA, Saynina O)

Overview of randomized trials of antiarrhythmic drugs and devices for the prevention of sudden cardiac death (Heidenreich PA, Keeffe B, McDonald KM, et al.)

Management of ventricular arrhythmias in diverse populations in California (Alexander M, Baker L, Clark C, et al.)

Effect of risk stratification on cost-effectiveness of the implantable cardioverter defibrillator (Owens DK, Sanders GD, Heidenreich PA)

For more information on the AHRQ PORT on cardiac arrhythmias, contact David Hsia, J.D., M.D. M.P., at dhsia@ahrq.gov.