Disparity in use of implantable devices to prevent sudden death in heart failure patients

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A study of heart failure patients who meet national guidelines for devices that stabilize and strengthen the heart's electrical system found that only half of eligible patients received the devices. The study, which is the first to examine the management of heart failure patients in outpatient cardiology practices throughout the United States, also found wide, unexplained variations in the use of the devices, known as implantable cardioverter-defibrillators (ICDs). The study is published in the December 2009 issue of the journal *HeartRhythm.*

Certain heart failure patients with weakened pumping ability and those who develop a condition called left ventricular systolic dysfunction after a heart attack are at risk for an irregular heart rhythm that can lead to sudden cardiac death. The heart suddenly stops beating after an electrical disturbance causes the heart to beat rapidly or chaotically. Extensive clinical trial experience and national guidelines recommend the placement of ICDs in patients with either of these conditions as a preventive measure.

"These patients have not had a major heart arrhythmia, but they are at high risk for a rhythm abnormality and therefore meet the criteria for device-based treatment," says the study's lead author, Mandeep R. Mehra, M.B.B.S., professor of medicine, head of the Division of Cardiology at the University of Maryland School of Medicine in Baltimore and chief of cardiology at the University of Maryland Medical

Center. "The device is implanted in order to be available if needed. For every 14 patients implanted with an ICD, one patient will experience a rhythm disorder that will trigger the device within two years."

The guidelines for device-based therapy of cardiac rhythm abnormalities were developed by the American College of Cardiologists, the American Heart Association and the Heart Rhythm Society. These guidelines are Class One recommendations, which Dr. Mehra says are must-do, based on tight evidence or clear consensus in the field that they should be done.

Study design

The study, known as IMPROVE-HF (Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting), captured data from about six percent of the 40,000 cardiologists practicing in the U.S. For two years, beginning in 2005, researchers reviewed the medical records of 15,381 patients in 167 community-based and academic-affiliated outpatient cardiology practices geographically dispersed throughout the U.S. A representative sample of records was screened from each practice to yield an average of 90 patients per practice.

The data, which included patient demographics, medical history, heart function, laboratory results and treatments, was reviewed by a group of 34 chart review specialists. The investigators also evaluated the reasons that patients did not have ICD implantation, such as patient refusal and medical, economic or religious reasons.

Study findings

According to current guidelines, 7,532 patients in the study were eligible for ICD implantation; 311 of those had documented medical contraindications or other reasons for not receiving an ICD. Among the

remaining 7,221 eligible patients, 3,659 (50.7 percent) had devices implanted.

Patients not offered the device despite the guidelines were most often older patients, blacks and those who did not have insurance. By contrast, men were more likely to receive a device than women. People whose hearts did not get enough blood and oxygen and those who had two types of heart rhythm disorders, atrial fibrillation and wide QRS, also were more likely to receive ICD therapy. The therapy also was more likely in patients treated with a variety of common heart disease medications, such as beta-blockers, statins and angiotensin-converting enzyme inhibitors.

Cardiology practices in the Northeast U.S. were more likely to adhere to guidelines, as were those with a dedicated heart failure clinic and those staffed with heart rhythm disorder specialists called electrophysiologists.

The researchers note several limitations to the interpretation of the data. A proportion of the records of patients who appeared to be ICD-eligible lacked critical details that may have accounted for the decision not to use the devices. For example, functional capacity, a key measurement of heart disease severity and prognosis, was documented for only 66.5 percent of patients. Similarly, race was not consistently documented throughout the study group, potentially obscuring the true influence of race in the decision to use ICD therapy. ICD usage in eligible patients may be overestimated in this study because the data came from self-selected cardiology practices willing to participate in a quality improvement initiative.

Dr. Mehra says concerns about costs may also have figured in the decision of some cardiologists not to use ICD therapy in certain eligible patients. The cost of the devices and the professional and technical fees associated with their implantation and maintenance totals about $50,000.

He says the devices have been shown to be cost-effective in the long run. But he adds that it may be necessary to develop more refined criteria for implantation, to make it easier to predict which patients might actually benefit from the devices.

"This research provides useful insight into an apparent gap in patients receiving a recommended therapy in the United States," says E. Albert Reece, M.D., Ph.D., M.B.A., vice president for medical affairs at the University of Maryland and dean of the University of Maryland School of Medicine. "Whether the gap is the result of medical or societal factors, concerns about costs, or other issues, Dr. Mehra's study is an important benchmark in the effort to understand how best to treat people with debilitating heart disease."

Heart failure affects nearly 5 million Americans. It develops when the heart is not able to pump enough blood to meet the body's needs. The heart compensates for this loss in pumping capacity by growing larger, increasing muscle mass and pumping faster to increase the heart's output. Eventually, the heart and the body cannot keep up with the demands, and the person begins to experience the fatigue and breathing problems that often are the first signs of the disease.

More information: Mehra MR, Yancy CW, Albert NM, Curtis AB, Stough WG, Gheorghiade M, Heywood JT, McBride ML, O'Connor CM, Reynolds D, Walsh MN, Fonarow GC. "Evidence of clinical practice heterogeneity in the use of implantable cardioverter defibrillators in heart failure and post-myocardial infarction left ventricular dysfunction: Findings from IMPROVE HF." HeartRhythm. Volume 6, Issue 12, Pages 1727-1734 (December 2009).

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