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Many Patients With Implantable Cardioverter-Defibrillators Do Not Meet Criteria for Use

A study that included more than 100,000 patients who received Implantable Cardioverter-Defibrillators (ICDs) found that about 20 percent did not meet evidence-based guidelines for receipt of an ICD, and that these patients had a significantly higher risk of in-hospital death than individuals who met criteria for receiving an ICD, according to a study in the January 5 issue of JAMA.

Several randomized controlled trials have shown the effectiveness of ICDs for preventing sudden cardiac death in patients with advanced systolic heart failure. But practice guidelines do not recommend use of an ICD for primary prevention in patients recovering from a heart attack or coronary artery bypass graft surgery and those with severe heart failure symptoms or a recent diagnosis of heart failure. "The degree to which physicians in routine clinical practice follow these evidence-based recommendations are not clear," the authors write.

Sana M. Al-Khatib, M.D., M.H.S., of the Duke Clinical Research Institute, Durham, N.C., and colleagues conducted a study to determine the number, characteristics, and in-hospital outcomes of patients who received a non-evidence-based ICD. The study included an analysis of cases submitted to the National Cardiovascular Data Registry-ICD Registry between January 2006 and June 2009.

The researchers found that of 111,707 initial primary prevention ICD implants that occurred during the study period, 25,145 were for a non-evidence-based indication (22.5 percent). Of these, 9,257 were in patients within 40 days of a heart attack (36.8 percent) and 15,604 were in patients with newly diagnosed heart failure (62.1 percent). The risk of in-hospital death was significantly higher in patients who received a non-evidence-based device than in patients who received an evidence-based device (0.57 percent vs. 0.18 percent). The risk of any postprocedure complication was significantly higher in the non-evidence-based ICD group at 3.23 percent compared with 2.41 percent in the evidence-based group.

"Although the absolute difference in complications between the 2 groups is modest, these complications could have significant effects on patients' quality of life and health care use, including length of hospital stay and costs. Importantly, these complications resulted from procedures that were not clearly indicated in the first place. While a small risk of complications is acceptable when a procedure has been shown to improve outcomes, no risk is acceptable if a procedure has no demonstrated benefit," the authors write.

Any adverse event and death were significantly higher in patients who received a non-evidence-based device. The median (midpoint) length of hospital stay was significantly longer for patients who received a non-evidence-based ICD compared with patients who received an evidence-based ICD (3 days vs. 1 day). Also, there was substantial variation in non-evidence-based ICDs by site.

The proportion of ICD implants performed by the different types of physician specialty was 66.6 percent for electrophysiologists, 24.8 percent for nonelectrophysiologist cardiologists, 2.6 percent for thoracic surgeons, and 6.1 percent for other specialists. The rate of non-evidence-based ICD implants was significantly lower for electrophysiologists (20.8 percent) than nonelectrophysiologists (24.8 percent for nonelectrophysiologist cardiologists; 36.1 percent for thoracic surgeons; and 24.9 percent for other specialties). There was no clear decrease in the rate of non-evidence-based ICDs over time.

"During this period of limited resources and due to the Centers for Medicare & Medicaid Services' emphasis on

quality improvement by promoting evidence-based care, it is increasingly important to assess hospital performance and to provide feedback to hospitals about their outcomes and compliance with clinical guideline recommendations. Providing such feedback to hospitals has the potential to improve adherence to practice guidelines and eventually patient outcomes," the researchers write.

"more efforts should focus on enhancing adherence to evidence-based practice."

Editorial: Selecting Patients for ICD Implantation -- Are Clinicians Choosing Appropriately?

To improve public health, the cardiovascular care community must act on the data from this study, write Alan Kadish, M.D., of Touro College, New York, and Feinberg School of Medicine, Northwestern University, Chicago, and Jeffrey Goldberger, M.D., of the Feinberg School of Medicine, Northwestern University, Chicago, in an accompanying editorial.

"There are several important considerations. Further information and specific data are needed to characterize some of the issues, such as how well the National Cardiovascular Data Registry captures some of the subtleties of ICD indications and whether reasons for deviations from the guidelines can be captured accurately. Once this is accomplished, it is possible that prospective data entry in an online system can be developed to provide immediate feedback regarding the presence or absence of an evidence-based indication for an individual patient prior to ICD implantation.

"It is likely that all physicians require further education to understand the rationale for the guidelines and potential alternative approaches when a patient does not meet guidelines for ICD implantation. In addition, as a matter of public policy, health care organizations must assess whether quality of care and cost-effectiveness can be improved by mandating the Heart Rhythm Society's guideline for formal training in an approved fellowship training program. If properly applied, the findings of the study by Al-Khatib et al may improve practice patterns and outcomes, with the unique opportunity to do so while lowering health care costs."

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