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Preventing Sudden Death: Implantable Cardioverter-Defibrillators in Elderly Cardiac Patients

Editor's Note: Much of the public was introduced to the implantable cardioverter-defibrillator (ICD) when Vice President Cheney, a survivor of four heart attacks, received the device in 2001. Although ICDs were initially limited to patients with previous cardiac arrests or arrhythmias, more recent studies have demonstrated that ICDs can prevent sudden cardiac death in patients who have not had a cardiac arrest, but are at greater risk for one (for example, those with congestive heart failure and reduced cardiac function). This Issue Brief summarizes studies that analyze health outcomes, costs, and quality of life for patients-at-risk who receive ICDs in real-life settings.

The ICD is one of the most common cardiovascular devices in use

An ICD is a small device implanted in a patient's chest to monitor the heart's rhythm and deliver an electrical shock if a life-threatening arrhythmia occurs. More than 100,000 ICDs were implanted in 2005, making them among the most common cardiovascular devices in use. In general, patients receive an ICD for one of two reasons: to prevent sudden cardiac death in patients with a history of cardiac arrest or irregular heart beat (secondary prevention) and to prevent the initial cardiac arrest in patients at greater risk due to congestive heart failure (CHF) or related conditions (primary prevention).

- Patients receiving ICDs for primary prevention are the fastest growing segment of the ICD recipient population. It is estimated that hundreds of thousands of patients with CHF and poor ventricular function, many over age 65, are now potential candidates for ICDs.
- Based on clinical studies, Medicare and other health care payers issued policy decisions in 2003 and 2005 extending coverage of ICDs to patients for primary prevention. In 2005, more than 40,000 Medicare beneficiaries received ICDs.
- Although clinical trials have shown that primary prevention ICDs are cost-effective, the costs and outcomes of ICDs when used in routine clinical practice in CHF patients is not known. Also little is known about the impact of ICDs on primary prevention patients' quality of life.

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Study assesses ICD outcomes and costs in the Medicare population

Groeneveld and colleagues assessed health outcomes and costs among elderly Medicare beneficiaries hospitalized for CHF and related diagnoses who had received primary ICDs between October 2003 (when Medicare first expanded ICD coverage) and September 2005. Study patients included a nationally representative sample of Medicare patients who were treated at more than 2,000 academic and community hospitals nationwide.

- The investigators studied 7,125 ICD recipients and compared them with an equal number of “control” patients with similar diagnoses who did not receive ICDs. The groups were closely matched across multiple demographic and clinical variables.
- Patients with advanced, end-stage heart failure were excluded from the study, because ICDs would have been clinically inappropriate.
- Medicare databases were used to compare outcomes between the two groups through December 2005, including length of hospital stay, rehospitalizations, complications, and mortality.
- Inpatient and outpatient claims data were used to calculate and compare the incremental costs of the ICD in this elderly cohort.

Primary prevention patients with ICDs live longer, with higher upfront medical costs

The study found that ICD patients, after adjusting for small residual differences in demographic and clinical factors, had a 38% lower mortality rate than patients who did not receive an ICD.

- Short-term mortality differed markedly between the two groups: 13% of ICD recipients died in the first year after implantation, compared to 23% of the matched controls. This difference widened in the second year, with 17% of ICD recipients and 29% of controls dying within 24 months of the initial hospitalization.
 - During their initial hospitalization, ICD patients were more likely to have critical care stays of more than 3 days, and hospital stays of more than 6 days. About 14.5% of ICD patients developed complications during the first 30 days after hospitalization, compared to about 1.5% of controls.
 - ICD patients had higher median hospital costs in the first 30 days after initial hospitalization (median difference = \$41,542) and at 1 year (median difference = \$41,503) as well as higher outpatient and physician costs at 6 months (median difference = \$1,828).
 - Although the study did not have sufficient follow-up to fully estimate cost-effectiveness, the upfront cost difference and survival benefit is consistent with the findings of previous ICD cost-effectiveness analyses. One well-known study found that the cost-effectiveness of ICDs was \$38,389 per life-year saved, well within the U.S. standards for cost-effective preventive care.
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Study compares the health-related QOL among primary and secondary prevention ICD patients

It is uncertain how the ICD affects the quality of life (QOL) experienced by primary prevention patients. Previous studies of QOL had been conducted among secondary prevention patients (who had already suffered cardiac arrest or arrhythmias). Those studies found that ICDs improved patients' QOL by enhancing security, but negatively affected QOL due to the unpredictability of the shocks. Groeneveld and colleagues measured and compared QOL in both primary and secondary prevention ICD recipients.

- In 2006, the investigators surveyed 45 primary prevention and 75 secondary prevention ICD patients receiving electrophysiological care at the University of Pennsylvania and reviewed medical records to determine the reason for the ICD implantation, the date of implantation, and ICD shock history.
- Each patient completed several QOL instruments to assess both overall health-related QOL and ICD-specific QOL.
- As the use of ICDs for primary prevention is a more recent phenomenon, patients receiving an ICD for secondary prevention reported a much greater duration of time living with their devices compared to primary prevention patients (median of 3 years vs. 1 year).

Both primary and secondary prevention patients had overall QOL scores virtually identical to similarly aged adults in the general population

The study found remarkably few QOL differences between primary and secondary prevention ICD patients and between these patients and similarly aged adults in the general population.

- Although the ICD was highly acceptable to most patients, substantial fractions of both primary and secondary prevention patients had concerns about lifting children or heavy objects (40%), sexual activity (19%), and driving (14%).
- Secondary prevention patients were more likely to report having received a shock from their devices (51% versus 11%). ICD shocks were associated with higher QOL in secondary prevention patients but associated with lower QOL in primary prevention patients. It may be that secondary prevention patients assessed their risk of sudden cardiac death as being higher and thus considered their ICD shocks to be comforting because they were potentially life-saving.

POLICY IMPLICATIONS

These findings confirm, through real-world experience among thousands of patients, the value of ICDs in the primary prevention of sudden cardiac death. The studies indicate that ICDs save lives, do so at a reasonable cost, and preserve quality of life.

- ICD costs to both hospitals and patients remain substantial. Further improvement in the cost-effectiveness of ICDs may come from incentives to encourage adherence to clinical guidelines in selecting candidates for ICDs. The American College of Cardiology, American Heart Association, and Heart Rhythm Society revised the guidelines for use of cardiac rhythm devices, including ICDs, in May 2008.

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POLICY IMPLICATIONS

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- Care may also be improved further by addressing the high complication rate for ICD implantation (about 1 in 8 patients in the first 30 days). Policies that encourage patients to seek the highest quality ICD providers, or reimbursement rates that reward higher quality ICD providers, may reduce complications related to ICD implantation.
- Because ICD shocks are sources of ongoing patient concern, clinicians should specifically reinforce messages about living with an ICD, including the impact of the device on driving, sexuality, and physical exertion. Primary prevention patients who have received a shock may require more explanation of the event and reassurance by clinicians than secondary prevention patients.

This Issue Brief is based on the following articles: P. W. Groeneveld, S.A. Farmer, J.J. Suh, M.A. Matta, F. Yang, Outcomes and costs of implantable cardioverter-defibrillators for primary prevention of sudden cardiac death among the elderly, Heart Rhythm, May 2008, vol. 5, pp.646-653; P.W. Groeneveld, M.A. Matta, J.J. Suh, F. Yang, J.A. Shea. Quality of life among implantable cardioverter-defibrillator recipients in the primary prevention therapeutic era. Pacing and Clinical Electrophysiology, April 2007, vol. 30, pp. 463-471; P.W. Groeneveld, M.A. Matta, J.J. Suh, P.A. Heidenreich, J.A. Shea. Costs and quality-of-life effects of implantable cardioverter-defibrillators. American Journal of Cardiology, November 2006, vol. 98, pp. 1409-15.

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