Estimates of Implantable Cardioverter-Defibrillator Complications

Caveat Emptor

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Appropriate selection of patients for implantable cardioverter-defibrillator (ICD) therapy requires knowledge of the beneficial effects and adverse consequences of such therapy. Although the randomized clinical trial is the sine qua non for establishing the benefits and exposing the adverse effects of interventions, subjects recruited for ICD trials may not represent the eligible population. Moreover, improved treatments of the underlying disorders and comorbid conditions and advances in equipment and implantation techniques could alter the balance of benefits and risks so that information from older clinical trials cannot be assumed to reflect current practice. In this issue of Circulation, Peterson and colleagues provide one of the first peer-reviewed studies using the National ICD Registry (NICDR) to examine gender-related differences in ICD implantation complication rates. Two preliminary reports have shown that patients in the NICDR differ significantly from those recruited into 2 of the primary prevention ICD trials that provided the evidence base for current practice guidelines and reimbursement policies of the Center for Medicaid and Medicare Services. Participation is voluntary for most registries. Registries that include hospitals that agree to time- and labor-intensive data recording requirements and external scrutiny cannot be expected to represent hospitals that do not. The NICDR is part compulsory and part voluntary. Participation in the NICDR is required to receive reimbursement for primary prevention ICDs in Center for Medicaid and Medicare Services beneficiaries; however, about 75% of hospitals have elected to enroll all ICD patients in the NICDR. As of June 2008, data from 1448 hospitals totaling >270 373 implants had been entered in the NICDR. The report by Peterson et al is based on 204 700 unique patients accrued between January 2006 and December 2007 from 1224 hospitals. After exclusion of patients with a previous ICD implantation, the report by Peterson et al is based on 161 470 patients, which is nearly 50 times larger than the 3367 patients enrolled in the ICD arms of 9 primary prevention trials. Peterson et al report that among the NICDR patients they analyzed, 3.55% experienced an adverse event, 1.35% had a major event, and 0.42% died. In contrast, a peri-implantation mechanical complication rate of 5.3% of 3299 ICD recipients and a mortality rate of 1.3% of 39 858 ICD recipients were estimated from a systematic review of randomized clinical trials and observational studies. In a relatively contemporary population of 30 984 Center for Medicaid and Medicare Services beneficiaries, administrative data were used to estimate a complication rate of 10.8% and a mortality rate of 0.9% for ICD implantation. These variant estimates of implantation-related complications and deaths underscore the need for clarity with regard to event definitions, timing of events, data sources, characterization of the population sample, and accuracy of recorded events.

All data are subject to errors, but systematic errors could skew estimates of complications in ways that are difficult to detect. Schemes that codify adverse effects can promote errors by neglecting key complications or by using ambiguous definitions. In particular, reports based on International Classification of Diseases–Clinical Modification codes require subjective decisions in the interpretation of codes created by committees and applied by coders with limited knowledge of ICD complications. Some complications could be systematically underreported owing to perceived threats to personal or institutional reputation, because of financial or legal ramifications, or because they are difficult to identify or characterize. Reporting of particular complications also could be enhanced by reimbursement policies or because they are more easily detected. Recently, investigators examined data from the registry established by the British Cardiac Society, the Society of Cardiothoracic Surgeons, and the British Pediatric Cardiac Association. Survival data after treatment for congenital heart disease submitted by participating hospitals on a voluntary basis were compared with independently validated life status. The investigators found that 7 of 11 centers underreported death within 30 days. Volunteered data underestimated 30-day mortality by 22%. Hospital statistics underestimated the total number of procedures by 10%, underreported death within 30 days by 9%, and misclassified 1% of surviving patients as deceased. If ascertainment of a discrete event such as mortality is imperfect, determination of more subtle and subjective adverse events is likely to be more prone to errors. This concern is highlighted by a study that showed significant differences in comorbid conditions recorded in an administrative database compared with individual chart review. The prevalence of comorbid conditions such as congestive heart failure, myo-

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cardiac infarction, and renal disease was underreported by 12%, 49%, and 33%, respectively. In addition, risk-adjustment methods based on comorbid conditions may also be distorted. These studies demonstrate that the accuracy of registry and administrative data cannot be assumed.

Peterson et al clearly show that women have higher rates of certain types of complications, and they propose plausible hypotheses for their observations. If it is true, for instance, that smaller body size is responsible for increased risk, and if changes in equipment design or techniques lower this risk, complications might be reduced for many men and children, as well as for some women. Clinicians will be tantalized by the listed rates of 20 complications, prospectively defined by ICD experts and stratified by sex. Because of the size and representation of the database, these data should have a precision and relevance to current practice that surpass previous sources. In addition, the clinical context is framed by detailed patient and hospital demographics and clinical characteristics. However, a number of questions remain to be addressed: Did complications occur that were not listed in the NICDR data forms, such as refractory ventricular fibrillation requiring multiple shocks, prolonged hypotension, or heart failure exacerbation? Was there evidence of underreporting, eg, hospitals with very low complication rates? Were complication rates different from the 25% of hospitals that did not elect to enroll all ICD recipients? What was the temporal distribution of complications? It is expected that complications that occur during the implantation procedure are reliably reported, but complications that occur later during the hospital stay require additional effort to track down, and events that occur after discharge, including death, are not recorded. Therefore, it is important to determine whether there is evidence of underreporting based on when the complication occurred, whether complication rates are affected by duration of hospitalization, and whether complications are being missed for outpatient procedures. Peterson et al showed that length of stay was prolonged in patients with complications, but it is not clear whether this was due to a longer hospitalization before implantation (ie, related to preexisting risk) or to prolonged length of stay after implantation.

Accurate estimation of adverse effects is a major challenge. The complications included in the current version of the NICDR are just the tip of the iceberg of the wide variety of adverse effects that occur over the ICD recipient’s lifetime. From a systematic review of clinical trials and observational studies, the estimated frequencies (per 100 patient-years) of postimplantation complications (as distinguished from the 5.3% rate of peri-implantation complications cited earlier) were 1.4 for device malfunctions, 1.5 for lead problems, and 0.6 for implant-site infection. Whether or not they prolong life, most ICD shocks are unpleasant and may contribute to a variety of mild to severe psychological reactions, and in some trials, they have been associated with increased mortality. In an analysis of clinical trials, inappropriate shocks were very frequent (19.1 per 100 patient-years), and therapeutic shocks occurred in 5% to 12% of patients per year. Other adverse effects of ICD therapy are more difficult to quantify. For instance, exclusion from magnetic resonance imaging, which applies to many current ICDs, may result in a more painful or harmful diagnostic procedure or failure to diagnose an important disorder. In some cases, patients are excluded from a preferred occupation or recreational activity, such as arc welding, ICD generator or lead recalls or safety alerts often provoke anxiety, and if explantation is necessary, there is a risk of procedural complications, including death. Psychological reactions are very common in patients with ICDs, but their existence may not be evident to the clinician or even to the patient unless specifically sought. Finally, there is a category of ICD complications that are believed to exist but are difficult to prove in individuals. For instance, clinical trials demonstrate that ICD therapy reduces the risk of sudden cardiac death by only 54%. In most cases, the mechanism of sudden cardiac death in patients with an ICD is not known. It is postulated that some of these deaths are due to device-related complications such as proarrhythmia, failure to detect or to terminate ventricular tachycardia/ventricular fibrillation, pacing-resistant asystole, or other forms of pulseless electrical activity after shock.

Several features of the NICDR contract, as well as measures taken by the staff of the American College of Cardiology Foundation, promote the quality of the data, and when the results of audits become available, a quantitative assessment should be possible. A new version of the NICDR database will improve adverse event detection by including follow-up data on leads. It will also be configured to enroll pediatric ICD recipients, who have a different distribution of complications from adults. Another project, the Longitudinal ICD Registry study, will follow up a cohort of 3500 Medicare beneficiaries receiving a primary prevention ICD. The purpose of the study is to analyze ICD therapies during 3 years of follow-up and mortality for up to 5 years. This will be combined with data from the NICDR, the National Death Index, and Medicare claims. Although it is not its primary objective, the Longitudinal ICD Registry will have the capacity to provide details about many adverse events in an important subset of the NICDR.

In summary, ICD therapy is associated with a large variety of adverse effects, some of which are experienced by all recipients with variable severity, some of which are very difficult to detect, and some of which are postulated but unproved. Although no single data source is likely to provide a comprehensive perspective of adverse events, the NICDR is uniquely capable of accomplishing this objective with unsurpassed power and detail. To fulfill the promise of providing reliable information for clinicians, patients, and the public, the NICDR must establish a framework for continuous monitoring of the database and public disclosure. This includes oversight of data acquisition, auditing of data, reporting of data accuracy, alerts when safety thresholds are exceeded, and appropriate risk adjustment before public reporting. This might be best accomplished by a named independent data and safety monitoring board that would be held accountable for these responsibilities.

The NICDR is a milestone in the history of ICD therapy that should improve the care of ICD patients on many levels. It is also likely to be the focal point of scrutiny of ICD outcomes, as well as physician performance and reimbursement. The many parties that contributed to the development
of the NICDR should be recognized, in particular, the Center for Medicaid and Medicare Services for creating the mandate, the NICDR Working Group for creating the registry, the American College of Cardiology Foundation for implementing the registry, and the participating hospitals for the time, effort, and considerable expense involved in collecting the data. The medical community should now address the complex and controversial issue of how the NICDR should be funded in view of the likelihood that information from the NICDR will improve selection of ICD candidates, reduce complications, and save millions of dollars.

Disclosures

None.

References


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