The REPLACE Death After Replacement Evaluation Score for Predicting Mortality After Device Replacement or Upgrade

Should All Implantable Devices Be Replaced?

Stefan Bogdan, MD; Michael Glikson, MD

The use of cardiovascular implantable electronic devices (CIED) has made remarkable progress during the past 20 years. Overall, devices, leads, and delivery systems have evolved resulting in easier implantation, improved long-term reliability and better battery life span.

Implantable cardioverter defibrillators (ICD), initially reserved for highly selected patients, where the benefit of secondary prevention outweighed potential side effects, are now a safe and widespread therapy that has become part of the standard care in patients with heart failure and severe systolic dysfunction. Present-day guidelines take into account all evidence from multiple large randomized trials (the Multicenter Automatic Defibrillator Implantation Trials [MADIT I, MADIT II], the Multicenter Unsustained Tachycardia Trial [MUSTT], and the Sudden Cardiac Death in Heart Failure Trial [SCD-HeFT]) that favor their use for the primary prevention of sudden cardiac death in patients with heart failure, which is currently the main indicator for ICD in developed countries.

Cardiac resynchronization therapy (CRT) has been shown to improve clinical status, left ventricular performance, and to reduce mortality in patients with heart failure and systolic dysfunction and wide QRS. After the initial studies that focused on patients with clinically severe heart failure (New York Heart Association class III or IV), the MADIT-CRT trial, the Resynchronization–Defibrillation for Ambulatory Heart Failure Trial (RAFT), and the Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction trial (REVERSE) clearly proved that CRT’s beneficial effects also extend to those less severe patients (baseline New York Heart Association class II), which led to the recent update of CRT guidelines.

All the evidence resulted in a dramatic increase of the number of complex device implantations in developed countries.

Since its creation in 2006, the NCDR ICD Registry has recently reported having accrued a total number of 850,068 ICD procedures. A tendency toward lower implantation rates for new high-powered devices was shown during recent years. However, the total number of procedures continues to increase annually, mainly because of replacements and lead-only procedures. This trend is augmented by the need to replace systems because of device or lead advisories and the need to upgrade ICDs to CRTDs.

Because of increased implantation and better survival rates in patients with heart failure, progressively larger numbers of CIED recipients require replacement procedures annually. Nationwide reports suggest that ≈40% of all ICD implantations are replacements of existing devices. Replacement is an invasive procedure with a risk of complications. These include main pocket hematoma (requiring reintervention) and infection (resulting in system removal), depending on the need for lead revision or upgrade; other potential complications can occur, such as cardiac perforation, pericardial tamponade, hemo/pneumothorax, generator/lead malfunction requiring reintervention, pocket revision, cardiac arrhythmias, hemodynamic instability during the procedure, and even death.

Despite extensive studies on complications after newly implanted CIEDs, systematic prospective studies investigating CIED replacement complications were omitted, until the Implantable Cardiac Pulse Generator Replacement Registry (REPLACE) study was implemented. The REPLACE registry was a prospective multicenter study designed to collect complication data on patients during 6 months after CIED replacement. It enrolled 1744 patients who were divided into 2 cohorts, based on the necessity for lead revision or upgrade (cohort 1: no need and cohort 2: with need). The results published in 2010 showed that major complications occurred in 4% of 1031 cohort 1 patients and in 15% of 713 cohort 2 patients. Simple CIED generator replacement, without lead revision or upgrade, carried a low risk for bleeding and major complications. Regardless of the cohort, major complications were higher with ICD when compared with pacemaker replacement. Also, complications were highest in patients who had an upgrade to or a revised CRT device. Although there were no periprocedural deaths in either cohort, later procedure-related deaths occurred in the second cohort. Of note, the 6-month infection rates were similar between cohorts (1.4% versus 1.1%). The authors concluded by recommending careful decision making before device replacement, advisory management, and upgrades.
In this issue of the journal, the results of the REPLACE Death After Replacement Evaluation (DARE) analysis were published. In this study, the authors have shown that in the REPLACE registry, comorbidities, but not complications, were associated with 6-month mortality after CIED replacement. On the basis of these findings, they have developed a mortality risk score, the REPLACE DARE Score, for identifying patients with limited expected longevity before the replacement, in whom the relative risk and benefit of the procedure should be carefully considered.

After extensive analysis of the individual clinical, electric, echocardiographic, and biological characteristics of patients enrolled in the REPLACE registry, the authors identified several significant predictors of survival time: age, admission for heart failure in the previous 12 months, New York Heart Association class III/IV, antiarrhythmic drug use, cerebrovascular disease, and chronic kidney disease stage.

Interestingly, major complications, despite being associated with a strong trend toward increased mortality in univariate analysis, failed to correlate with 6-month survival in the adjusted analysis. Comorbidities rather than complications were identified as the most probable contributors to mortality after CIED replacement. This may suggest a higher disease burden in patients having experienced complications.

These results are reassuring for the majority of procedure candidates, in a way that the replacement itself, despite complications, does not seem to significantly alter the patient’s survival and outcome is mainly dependent on the underlying heart and general condition. So if a patient clearly benefits from a CIED therapy, comorbidities should not interfere with performing the replacement when indicated.

In addition, the results are in keeping with previous results from other CIED and non-CIED studies, namely that severe heart failure, arrhythmia and antiarrhythmic therapy, cerebrovascular disease, and chronic kidney disease are associated with higher mortality rates, in the general population and in specific subgroups. Moreover, the results are confirmed by a recent study published from the NCDR® ICD registry, which has shown that in addition to age, atrial fibrillation, and congestive heart failure, noncardiac comorbidities were associated with higher mortality after ICD replacement. These included chronic lung disease, cerebrovascular disease, diabetes mellitus, and lower glomerular filtration rate.

Survival predictors were combined to create a mortality score, the DARE score, which was then validated within the REPLACE registry cohorts. It showed good predictive value for identifying both low-risk (score 0, risk of death 1%) and high-risk (score 7, risk of death 55%) patients. An online tool provides an easy way for the clinician to calculate the DARE score by entering the 6 required parameters, resulting in an assessment of the projected 6-month mortality risk after CIED replacement for a specific patient.

The main clinical interest in calculating the DARE score is identifying the high-risk patient, particularly if he carries a primary prevention ICD. In view of current guidelines requiring a life-expectancy of ≥1 year, a high-risk DARE score may significantly influence the replacement decision. Nonperformance of the required CIED replacement is equivalent to device deactivation, and one should carefully consider the instance in which this might be acceptable.

The pros and cons of device replacement differ from those of initial implantation, and the decision to replace a device should not be based on battery status alone. There is far less evidence supporting the decision to replace an ICD than there is for primary implantation and outcomes information on the natural course and outcomes after device replacement.

In that aspect, the REPLACE registry is an extremely important contribution. Over an average device life span of 5 years since implantation, a patient’s health status may have deteriorated, their experience with the ICD or the life expectations may have changed his/her preferences on replacement, and in some fortunate cases ventricular function may have improved considerably, making the need for replacement questionable. The REPLACE DARE score has not yet been externally validated, and its highest risk group is based on a small patient group. Therefore, it cannot be used alone in determining whether to refrain from replacement in an individual patient, but it can support decision making about replacements in borderline cases, especially when it concurs with the will of the patient and the family, and with clinical common sense of the caretakers. It is, therefore, an important and welcome addition to the limited tool box of physicians that have to cope with deciding whether to replace devices, in view of scarce information and in the absence of firm clinical guidance.

Although generally providing strong evidence toward the safety of CIED replacements, the REPLACE DARE study is a reminder that each patient has to be carefully reassessed to minimize procedure-related risks and to adjust device therapy according to current clinical status. Additional studies are needed to confirm the validity of the DARE score and the feasibility of withholding device replacement in selected patients.

Disclosures

None.

References


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