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In sickness and in health, till death do us part: Is the ICD a lifelong commitment?



A B S T R A C T

The decision-making process around initial implantation of an Implantable Cardioverter Defibrillator (ICD) is well studied, guided by randomized clinical trials which have translated into widely accepted clinical guidelines. For patients who out-live their first device and are eligible for a generator exchange (GE) the indications to replace the battery is much less well-defined. In this latter case, the clinician needs to make the decision based on persistent indications for primary prevention ICD, risk of future arrhythmic death in the absence of ongoing indications for primary prevention, competing causes of non-arrhythmic death and the patient's overall goals of care.

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In this manuscript, Dell'era et al. [1] select a group of patients with a primary prevention indication for an ICD who then go on to get a generator exchange, and examine the risk of future arrhythmic events in those with persistent indications for ICD at the time of GE, and those without ongoing indications. In the group of patients who have received prior therapy from their device, the decision to perform a generator exchange is straightforward—prior history of arrhythmic events is the strongest predictor of future arrhythmic events. Indeed Dell'era et al. confirm that the only predictor of recurrent arrhythmic events after generator exchange is a higher incidence of appropriate therapy during the initial battery life. The authors also identify another relatively high risk group—those with persistently low EF but without history of appropriate therapies from their original device. These patients have an annual event rate after generator exchange of 1.08 events/year ($p < 0.0001$). Since LVEF is perhaps the most reliable risk stratification tool to predict risk of arrhythmic death, it is therefore not surprising that if the substrate for arrhythmic death persists, the risk of future events also persists.

The real treatment conundrum arises in the group of patients with improved LVEF and absence of arrhythmia during their initial implant. The authors identify this group and describe a small but significant event rate of 0.53 events/year ($p < 0.0001$) after generator exchange. Kini et al. recently reported the incidence of appropriate ICD therapy among those in whom ICD therapy was considered no longer indicated was 2.8%/person-year, compared with 10.7%/person-year in those in whom ongoing ICD therapy was considered indicated ($p < 0.001$) [2]. Therefore, while an

inverse relationship exists between LVEF and arrhythmic events, the rate of events even in this group with improved LVEF is higher than that of the general population [3]. Dell'era et al. can attribute some of the persistent risk of arrhythmic events due to improved but not fully recovered LVEF (mean $44 \pm 7\%$). However as they point out, 3 patients had near full recovery of EF ($>50\%$) and had appropriately treated arrhythmic events after generator exchange, suggesting that LVEF is an imperfect risk stratification tool.

However, while we acknowledge that the risk may not be negligible in this group, this alone is not a justification for generator exchange. The decision to undergo a generator replacement needs to be framed in the context of the overall goals of care of the patient. As the patient outlives the first battery life and continues to age and accrue co-morbid conditions, non-arrhythmic causes of death may outweigh the risk of arrhythmic sudden death. In fact, all-cause mortality at 1 and 3 years after GE is significantly higher than at the same time points following initial ICD implant: 9.9% versus 9.4% at 1 year and 27.4% versus 23.5% at 3 years [4]. In these patients, the decision to proceed with a generator exchange needs to be a multidisciplinary discussion with the patient and his various sub-specialty providers that are managing the competing non arrhythmic causes of death. The procedural risks associated with GE and the possibility of inappropriate shocks need to be balanced with expected longevity and quality of life.

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