Pre-discharge defibrillation testing: clinically important or obsolete?

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This editorial refers to ‘Pre-hospital discharge testing after implantable cardioverter defibrillator implantation: A measure of safety or out of date? A retrospective analysis of 975 patients’ by M. Guenther et al., on page 217

One of the most controversial and hotly debated topics in implantable cardioverter-defibrillator (ICD) management is the role of defibrillation testing. As with most areas of clinical controversy, the lack of controlled studies to guide the decision process is largely responsible for the ongoing differences in opinion. In the early period of ICD use, defibrillation testing was mandatory given the frequency of shocks, high defibrillation thresholds (DFTs) with monophasic waveforms and the relatively unsophisticated sensing algorithms for the detection of ventricular fibrillation (VF). An inadequate defibrillation safety margin was associated with worse outcomes.1 In the primary prevention era this mandate is less clear. Most patients will not have an appropriate discharge over the first 3–5 years of follow-up2 and defibrillation systems have improved significantly so that failed shocks are now infrequent events.

The use of defibrillation testing is not uniform and varies both by geographic region and prior experience. Proponents of testing point to the poor predictive value of clinical factors to identify patients likely to fail defibrillation, as well as the belief that if the device is implanted to save lives then we are obliged to show that it works. Opponents cite the potential morbidity/mortality associated with the procedure, and excess cost/time required for performing the procedure. The common questions asked by proponents of both sides of this argument are whether defibrillation testing is necessary with regard to effectiveness or safety and whether testing is justifiable for this expensive and time-consuming procedure.

Cardiac defibrillation, in and of itself, continues to be incompletely understood. Early animal trials supported the concept of 'Critical Mass Theory' in which a critical mass of myocardium must be depolarized in order to render the remaining mass of myocardium an insufficient area to support a reentrant wave-front, thus extinguishing the arrhythmia. More recent studies have challenged this theory in favour of a concept, in which a critical voltage gradient must be achieved across the myocardium in order to achieve absolute termination of the arrhythmia.3 The mechanics for achieving this adequate voltage gradient in the human subject are far too complex for complete understanding at present. Furthermore, the mechanism of VF itself continues to be debated. There is strong evidence that this arrhythmia exists only as a reentrant arrhythmia. Whereas in vivo evidence supports this concept, in vitro data have failed to corroborate this hypothesis.4 However, one concept that appears clear is that defibrillation is a ‘probability phenomenon’. In other words, with increasing energy, the probability of successful defibrillation increases, but it is rarely 0 or 100% except as extremes. All of the available data confirm that defibrillation is a function of energy delivered, the shocking vector, and the time-course in which it is delivered.

The study of Guenther et al.5 attempts to address this issue with a retrospective analysis of 975 patients. They observed that subjects with inherited cardiomyopathies or those with non-traditional forms of cardiomyopathy are at the greatest risk of unsuccessful defibrillation and thus are worthy of post-implant ICD testing. Furthermore, though the trial was not standardized as to DFT testing protocol, there did not appear to be an incremental risk associated with post-implant testing. However, on closer inspection only 1.4% of patients in this study are at risk of having an inadequate safety margin. Given the probabilistic nature of such testing, this is likely an overestimation according to the regression to the mean principles of statistics.6 In other words, patients at the extremes of defibrillation energy requirements (very low or very high) will likely have a more typical value measured the next time it is assessed. If this accounts for half the apparent high DFT cases, then only 0.7% would truly have an inadequate safety margin. Obviously, such an effect can be minimized with more robust testing algorithms7 but this is...
impractical for routine care. Only about 30% of patients receive appropriate shocks from their ICD so now only 0.2% of patients are truly at risk. These analyses assume that one failed shock would be lethal, which is clearly not the case as at times a second or third shock may terminate the arrhythmia or it may even terminate spontaneously. Thus assuming that all of these factors are independent, the proportion of patients who may die from a high DFT is <0.1%. This approaches the risk of the testing procedure and is probably far less than the risk of failed defibrillation for other reasons, such as ischaemia, electrolyte abnormalities, haemodynamic compromise, etc.

So what conclusions can we make from this study and others on defibrillation testing? First, such testing should be avoided in high-risk patients for complications, such as those with haemodynamic instability, active ischaemia, or in atrial fibrillation in the absence of adequate anti-coagulation. In addition, routinely repeated testing at implant and then pre-discharge or at other later times should be discouraged. However, equipoise still exists regarding the need to test most patients. Many patients die in the years following ICD implantation without an identifiable cause. Does optimizing defibrillation function reduce this risk and should this be our goal for ICDs? We will only know the answer to this question when a long-term trial is performed, with standardized post-implant testing and follow-up to confirm survival rates and outcomes. In this regard, we anxiously await the SIMPLE (Shockless IMPLant Evaluation) and Nordic-ICD trials.

Conflict of interest: M.R.G. currently conducts research for Medtronic, Boston Scientific, St. Jude Medical and Sorin.

References