Defibrillation Testing During Defibrillator Implantation

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Abstract

Implantable cardioverter defibrillators (ICDs) terminate ventricular tachycardia (VT) and ventricular fibrillation (VF) with high efficacy. ICDs improve mortality in patients after survived sudden cardiac death (SCD) and in patients at high risk of dying suddenly. All trials which show a benefit of ICD therapy, have performed some kind of defibrillation testing in order to prove correct system function, sensing of VF and effective defibrillation. Current devices show a shock efficacy of 80–90 % for singular shocks and devices provide up to seven rescue shocks. The probability that a device does not terminate an episode of VT or VF should therefore be very low. However, it is difficult to abandon defibrillation testing because prospective data is lacking that demonstrate non-inferiority, if ICDs are implanted without some kind of test. Two prospective trials are on the way and will be finish by 2013/14: the SIMPLE and NORDIC trial, which will answer the question if defibrillation testing can be abandoned without any effect on the benefit of ICD therapy or if testing may even be harmful.

Keywords

Ventricular fibrillation, defibrillation test, defibrillation threshold, DFT, implantable cardioverter defibrillator, ICD, sudden cardiac death, SCD

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For more than three decades, the implantable cardioverter defibrillator (ICD) has proven to be a well-established, main therapeutic tool for the primary and secondary prevention of sudden cardiac death due to malignant ventricular arrhythmias.¹

One of the standard practice concepts is defibrillation (DF) testing. Defibrillation testing has been considered a mandatory part at the time of implantable cardioverter-defibrillators (ICD) implantation in order to predict the likelihood of successful termination of clinical sustained ventricular arrhythmias during follow-up.² The test is intended to test the system, in particular the shock circuit integrity, ventricular tachycardia (VT)/ventricular fibrillation (VF) detection and VF termination. Yet, this concept has never been shown to improve clinical outcome.

The established reliability of current ICDs has led many electrophysiologists to call this practice into question.^{3,4} However, DF testing should be abandoned only, if prospective evidence demonstrates that ICD implantation without DF testing is as safe and has the same mortality benefit as implantation with testing.

Potential Risks of Implantable Cardioverter-defibrillator Tests

The risks of DF testing include those related to general anaesthesia required for testing, to the circulatory arrest during VF and those related to shocks or a combination of these factors. The induction of VT/VF causes haemodynamic compromise and other complications such as death, stroke and prolonged resuscitation.⁵ During VF, systemic perfusion is reduced resulting in organ ischaemia. Central nervous system activity is impaired as documented by electroencephalograph (EEG) slowing.^{6,7} Cerebral blood flow may be depressed for several

minutes after normalisation of mean arterial pressure and EEG, particularly after repeated inductions of VF.⁷ In patients with coronary artery disease, hypotension after VF may result in myocardial ischaemia and even infarction.⁸ Cardiac contractile function may be depressed and death due to electromechanical dissociation may occur in up to 0.1 % of patients who undergo DF testing at implant.^{9,10} Refractory VF may require prolonged resuscitation and usage of inotropic drugs. Shocks can cause arterial thromboembolism if intracardiac thrombus is present.⁵ Altogether major adverse events have been reported to occur infrequently and mainly unexpectedly in up to 0.4 % of all DF tests.¹¹ So, in general, a DF test is fairly safe, if common sense is used and patients are selected carefully.

Potential benefit of Implantable Cardioverter-defibrillator testing System Integrity

DF testing provides information about system integrity and especially the integrity of the shock circuit. This seems to be no longer necessary nowadays because the integrity of the shock circuit may be tested by low energy shocks and impedance measurements of the shock circuit. However, it has never been proven whether low voltage shocks and impedance measurements can unmask minor defects in the shock circuit such as isolation defects, i.e. during generator replacement.

Ventricular Defibrillation Sensing

Proper sensing of VF is the prerequisite of fast and effective VF termination. The bipolar signal during VF is smaller and more irregular compared to the signal during sinus rhythm or monomorphic ventricular tachycardias. However, since the work by Natale and colleagues, it is well known that an R-wave of more than 6 mV during sinus rhythm is a strong predictor of correct sensing during VF. During 1,178 induced

VF episodes in 160 patients, no underdetection or detection delay was observed during initial detection. All patients showed R wave sensing of 11.4 ± 3.2 during sinus rhythm. A delay of detection was only observed after ineffective first shock and was mainly attributed to signal variation after shock application.¹²

Shock Efficacy

All the data proving increased survival with ICDs were attained with some assessment of defibrillation efficacy at time of implantation as part of the ICD procedural protocol.^{1,13,14} Clinical data demonstrate a shock efficacy of up to 91 % regardless of whether intra-operative DF testing was performed or not.^{2,3} In patients with higher defibrillation thresholds (DFTs), which occurs in 1.6 to 6.1 % of patients, system modifications were often performed,^{15–17} such as the addition or reposition of electrodes (20 % of patients with high DFT), the programming of a reversed shock polarity (35 %) or the use of devices with higher energy output (36 %).^{15,18} Early trials showed that 42 % with an elevated DFT died suddenly.¹⁹ *Post mortem* interrogation studies of ICDs indicate that 25 % of sudden deaths in ICD patients were caused by a failure to defibrillate VF.²⁰ However, the main finding of the Sudden cardiac death in heart failure trial (SCD-HeFT) sub-study was that there was no difference in survival between patients with lower or higher DFTs and 97.8 % of patients had a DFT of 20 J or less with modern biphasic devices.³ First shock efficacy for spontaneous events was 83 % with 30 to 35 Joule first shock energy. Of 31 patients with first shock failure all survived the acute event as the arrhythmia terminated spontaneously or subsequent shocks were successful. These observations challenge the necessity for intra-operative DF testing at least in primary prevention of sudden cardiac death.

In a recent publication by Val-Mejias and Oza, the relationship between left ventricular ejection fraction (LVEF) and the DFTs was investigated. DFT changed minimally over a broad range of LVEF. There appeared to be no significant difference in patients with typically higher LVEF and typically lower LVEF and between patient groups receiving a device for primary or secondary indications.²¹

Bianchi and colleagues retrospectively compared the clinical outcome of ICD implantation for primary prevention of SCD with or without DF testing.²² 291 patients with ischaemic dilated cardiomyopathy were included. DF testing was performed in 137 patients and 154 patients received the ICD without DF testing. Most importantly there was no statistical significant difference between the DF testing and no-DF testing group regarding overall mortality, cardiovascular mortality, VT and VF incidence. However, trials with only a few hundred patients may be underpowered to show a difference of 5 to 10 % of shock efficacy during follow-up.

Finally, the medico-legal implications of a documented failure to defibrillate are uncertain as current guidelines recommend DF testing at implant.^{9,23}

One recent observational study, the Safety of two strategies of ICD management at implantation (SAFE-ICD) trial, in 2,120 consecutive patients compared DF testing at implantation with no DF testing in a non-randomised manner. The combined endpoint of intra-operative complications and sudden death during follow-up occurred infrequently: 12 intra-operative complications occurred, eight in the tested group. The risk of sudden death was 1.15 % per year in the tested group and

0.68 % in the not tested group. These data suggest a limited relevance of DF testing during implantation.²⁴

Current Trials

Two trials are on the way to answer the question of DF testing during ICD-implantation, the Nordic and Simple trials. Both trials randomise patients to DF testing and no testing at the time of ICD implantation. However, the endpoints are different. Whereas the SIMPLE trial investigates ineffective first shocks and sudden cardiac death, the NORDIC study looks at shock efficacy of all spontaneous VF episodes during follow-up. Thus both studies are complementary as far as the endpoints are concerned.

SIMPLE Study

The currently ongoing SIMPLE study is investigating if defibrillation testing can be eliminated as a component of ICD implantation, while still maintaining the clinical effectiveness of ICDs. Their primary endpoint is first occurrence of the composite of failed first appropriate clinical shock from the ICD or arrhythmic death. The SIMPLE trial only investigates first shock efficacy and adverse events of DF testing. The investigators of the trial have recently prolonged the observation phase, since the event rate was too low to show non-inferiority of the patient group without DF testing (personal communication). However, 'arrhythmic death' will be difficult to verify unless ICDs are interrogated *post mortem*; otherwise they are really 'unexplained sudden death'.

NORDIC Study

The NORDIC study compares the clinical outcome between patients who receive DF testing and those who do not receive DF testing during ICD implantation. The NORDIC study evaluates the impact of intra-operative DF testing on the long-term ICD shock efficacy for all true ventricular tachyarrhythmias in the observational period. Therefore, the primary analysis of this study will consider all ventricular tachyarrhythmia episodes treated by ICD shocks during the trial follow-up period. Thus, this trial evaluates shock efficacy for VF, which is the actual aim of any DF testing. Information on shocked episodes are transmitted by the Home Monitoring system of BIOTRONIK. This system is also used to monitor technical system integrity, device programming and cardiac performance continuously. It supports early information about the occurrence of VT/VF episodes and corresponding therapies such as ICD shocks even in patients who may die due to ineffective shocks. The Home Monitoring capability has the potential to detect some of these trends early and thus to offer the possibility to intervene in time for prevention of fatal worsening of cardiac performance. It offers the scientific opportunity of data completeness, which is vital for a study which aims at overall shock efficacy during clinical follow-up. The inclusion phase of this trial ends by July 2012 when 580 patients will be recruited.

Conclusion

Defibrillation of VF is a stochastic process, i.e. every shock energy terminates VF only with a certain probability. Therefore, effective shocks may not predict effective VF-termination in the future. All trials which show a benefit of ICD therapy, have performed some kind of defibrillation testing in order to prove correct system function, sensing of VF and effective defibrillation. Current devices show a shock efficacy of 80–90 % for singular shock and devices have up to seven rescue shocks. Therefore, the event rate associated with DF testing and thus the clinical relevance of DF testing may be so low, that prospective randomised trials will never reach the power to finally answer the question, whether DF testing can be abandoned without harm. ■

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