Defibrillation testing is not required during routine ICD implantation

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This editorial refers to ‘Intra-operative defibrillation testing and clinical shock efficacy in patients with implantable cardioverter-defibrillators: the NORDIC ICD randomized clinical trial’, by D. Bänisch et al., on page 2500.

Sudden cardiac death (SCD) is a major cause of mortality throughout the world, accounting for ~300,000 deaths per year in the USA.1 The introduction of the implantable cardioverter defibrillator (ICD) in the 1980s significantly reduced the risk of SCD by terminating life-threatening ventricular tachyarrhythmias.2 Subsequent clinical trials confirmed the survival benefit with implanted ICDs in at-risk cardiac patients.3,4 Since the beginning, defibrillation threshold (DFT) testing has been an integral part of the ICD implantation procedure to ascertain detection and termination of ventricular tachyarrhythmias. DFT testing often involves multiple ventricular fibrillation (VF) induction and defibrillation, imposing a significant burden on the implanting team and, foremost, the patient. However, the view on the routine use of DFT testing has been challenged by a recent investigation on DFT testing during ICD implantation.5

In this issue of the journal, Bänisch et al.6 present another prospective, randomized, parallel group, multicentre non-inferiority trial, NORDIC ICD, designed to test the hypothesis that shock efficacy during follow-up is not impaired in patients implanted without DFT during first ICD implantation. In this study, 1077 patients were randomly assigned to first time ICD implantation with (n = 540) or without (n = 537) DFT testing. During a median follow-up of 22.8 months, the first shock efficacy for all true ventricular tachycardia and fibrillation (VT/VF) was non-inferior in patients with an ICD implanted without DFT testing, with a difference in first shock efficacy of 3.0% in favour of the no DFT arm (95% confidence interval (CI) –3.0% to 9.0%, P < 0.001 for non-inferiority). There was a trend towards a higher rate of procedure-related serious adverse events within 30 days in the DFT testing arm (112 vs. 89 events, P = 0.095).

The authors are to be applauded for conducting a well-designed randomized clinical trial with enrolment of over a thousand patients to extend our knowledge further on the need for DFT during first ICD implantation. These findings further confirm the results of another recently published, large randomized clinical trial, the Shockless Implant Evaluation (SIMPLE) study by Healey et al.7 There are, however, differences between the two clinical trials. While in the SIMPLE trial, the endpoint was the composite of failed first appropriate clinical shock from the ICD or arrhythmic death, the NORDIC ICD trial utilized the endpoint of first shock efficacy for true VT/VF episodes. However, it is reassuring to know that in NORDIC ICD, there was no significant increase in all-cause mortality or arrhythmic death in the no DFT testing arm. The authors actually report a significantly higher rate of combined arrhythmic and sudden unknown deaths in the DFT testing group as compared with no DFT testing (P = 0.03). However, these findings have to be taken with a ‘pinch of salt’, since the event rate of combined arrhythmic and sudden unknown deaths was extremely low in the trial (DFT testing arm 11 patients, 2% compared with 3 patients, 0.6% in the no DFT testing arm). The authors suspect myocardial damage as the underlying pathomechanism for the increased risk of arrhythmic and sudden unknown death, recently suggested by a small study showing increased levels of brain natriuretic peptide (BNP) and troponin levels in ICD patients after DFT testing.7 However, a substudy from our Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT) showed that even increasing the number of ICD shocks and delivery of high energy ICD shocks during DFT testing were not associated with increased risk for heart failure or death.8 This deserves further investigation in prospective large patient cohorts, such as in the currently ongoing pre-specified substudy on troponin levels after DFT testing in the SIMPLE trial. Furthermore, the NORDIC ICD trial had a shorter follow-up as compared with SIMPLE (22.8 vs. 37 months) and, although the patient populations in the two studies were comparable, the overall mortality rate was lower in NORDIC ICD, indicative of a less sick patient cohort.

The evidence in favour of no routine DFT testing in most ICD patients is now significant. However, generalization of these findings to all ICD implantations would be a mistake (see Figure 1). It is
important to remember that the NORDIC ICD study enrolled only patients with first ICD implantations. These results are not applicable to patients with ICD generator exchange. Indeed, registry data suggested a high rate of failed intra-operative shock, failed shock at $\geq 21$ J, or failure to achieve a 10 J safety margin in patients undergoing ICD replacement in about one-third of the patients.9 Furthermore, the NORDIC ICD trial did not enrol patients with right-sided ICD implantation, in whom routine DFT testing is warranted. The proportion of patients with secondary prevention ICD implantation was 18%, less than what was seen in the SIMPLE study. Further analysis is needed on the value of DFT testing in patients with secondary prevention ICD implantation. In addition, there were no patients with channelopathies or hypertrophic cardiomyopathy in the NORDIC ICD study, excluding the possibility to extend the findings to this cohort.

Implantation of a subcutaneous ICD (S-ICD) device currently remains an indication for routine DFT testing to ensure proper detection and termination of ventricular tachyarrhythmias using this new technology.10

In our view, it is clear that the NORDIC ICD trial conducted by Bänsch et al.6 has advanced the field of cardiac electrophysiology by confirming that DFT testing is not required during routine first ICD implantation. Current guidelines should be re-evaluated based on the findings from NORDIC ICD and SIMPLE.5 The clinical implications of removing the requirement for DFT testing for initial ICD implantation should result in safer and improved patient care.

Conflict of interest: none declared.

References

Figure 1 Flow diagram for defibrillator threshold (DFT) testing. HCM, hypertrophic cardiomyopathy; S-ICD, subcutaneous implantable cardioverter defibrillator.