CLINICAL STUDY

Impact of the Relationship between the Defibrillation Threshold (DFT) and Clinical Outcomes in Recipients of Modern Era Implantable Cardioverter Defibrillator (ICD)

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Summary

Defibrillation threshold (DFT) testing during implantable cardioverter defibrillator (ICD) implantations is considered necessary for appropriate shock therapy and to measure the safety margin. However, the relationship between the DFT with modern era devices and the clinical outcome, including the total mortality is limited, which may lead to DFT testing itself being questioned. This study aimed to evaluate the relationship between the DFT and clinical outcome in ICD recipients.

We enrolled 81 consecutive patients (66 males, aged 64.6 ± 13.8 years) who received an ICD implantation and underwent DFT testing. The DFT was measured with a step-by-step method in the patients upon implant. Further, we evaluated the relationship between the DFT and the clinical outcome, which included major cardiac adverse events and any cause of death.

The mean DFT was 11.6 ± 9.24J in total. In 40 patients (49.4%), VF was terminated by a low output (5J), whereas 11 patients (13.6%) had a high DFT. The rates of atrial fibrillation were significantly higher in the high DFT group (63.6% versus 24.2%, $P = 0.007$). During the observational period (median 432 days; range from 151 days to 1146 days), the incidence of clinical events occurred in 22 patients (27.2%) in total. In a multivariate analysis, a high DFT was the only predictive factor for the incidence of the clinical outcome (OR 4.54, 95% CI 1.03-21.9, $P = 0.045$).

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Key words: Defibrillation threshold testing, Major adverse cardiac events, High DFT

Implantable cardioverter defibrillators (ICDs) have been shown to reduce the total mortality when used for the primary and secondary prevention of sudden cardiac death (SCD).[1,2] Therefore, ICD implantations play a key role in patients who have a risk of SCD. Defibrillation threshold (DFT) testing is performed after the ICD implantation to assure adequate sensing and defibrillation of ventricular fibrillation (VF). However, previous reports showed that the DFT testing during ICD implantations is neither effective nor beneficial.[3-9] The SIMPLE trial[10] is a single-blind, randomized, multicenter, non-inferiority trial comparing the efficacy and safety of ICD implantations with DFT or without DFT testing. Recently it demonstrated that a routine DFT test at the time of the ICD implantation does not improve shock efficacy or reduce arrhythmic death. However, Ziegelhoeffer, *et al*. reported that intraoperative DFT testing might still be recommended because the previous prospective clinical trials were limited to *de novo* implants of high-energy generators and neglected a large number of patients already implanted with an ICD system.[11] Furthermore, the determination of the actual DFT enables lower energy shocks and thus potentially reduces the energy required for defibrillation, shortens the charging time, reduces the risk of loss of consciousness, and decreases the myocardial damage.

In the present study, we enrolled various types of ICD recipients (an initial ICD or cardiac resynchronization therapy devices with defibrillation backup [CRT-D], generator replacements, or system revisions) and measured the actual DFT with a step-by step DFT testing method using modern devices. Furthermore, we evaluated the relationship between the DFT and clinical outcome in ICD recipients.

Methods

Patients and study protocol: The present study was a single center, retrospective clinical trial that evaluated the actual DFT with modern devices and the relationship between the DFT and clinical outcomes in those who had ICD implantations and DFT testing during the ICD implantation. We enrolled 81 consecutive patients (66 males,

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Table I. Baseline Patients' Characteristics (n = 81)

Variable	Mean ± SD or n (%)
Age (years)	64.6 ± 13.8
Men	66 (81.5)
LVEF (%)	43 ± 19.5
eGFR (mL/minute/1.73 m^2)	66.3 ± 30.2
Ischemic cardiomyopathy	32 (39.5)
Amiodarone usage	36 (44.4)
β-blocker usage	50 (61.7)
Atrial fibrillation/atrial flutter	24 (29.6)
Diabetes	14 (17.3)
Hypertension	54 (66.7)
Device and lead characteristics	
ICD indication (Primary prevention)	33 (40.7)
ICD type (Single chamber)	39 (48.1)
Single coil	9 (11.1)
CRT device	23 (28.4)

LVEF indicates left ventricular ejection fraction; eGFR, estimated glomerular filtration rate (mL/minute/1.73 m^2); ICD, implantable cardioverter defibrillator; and CRT, cardiac resynchronization therapy.

aged 64.6 ± 13.8 years) who received an ICD implantation and had a DFT test between January 2012 and January 2015 at our institution. Patients 18 years of age or more with a conventional indication for an ICD, regardless of the manufacturer, and who underwent an initial ICD or CRT-D implantation, generator replacement, or system revision were enrolled. The ICD and CRT-D devices were implanted in a standard transvenous fashion. The study protocol was approved by the Ethics Committee for Clinical Research of Toho University Ohashi Medical Center and was in compliance with the principles of the declaration of Helsinki. All patients provided their informed consent before the procedure.

DFT testing and follow-up: At the end of the procedure (new implantation of a device or replacement of the generator), DFT testing was performed in the standard fashion using a low energy T-wave shock or high-frequency burst method. The protocol for the DFT testing was performed with a step-by-step method. The energy of the first DFT test was 5J. If it was unsuccessful, the energy level was raised to 10-20J (depending on the manufacture) and then raised to 25J or the maximum energy level to terminate VF with the each device. All defibrillations were performed using a single coil configuration (RV coil to pulse generator) regardless of the type of actual lead (single or dual coil). If the patients had a high DFT, which meant less than a 10J safety margin between the DFT and maximum energy output of the implanted device, the physician was encouraged to re-position the right ventricular (RV) lead. The physician was also expected to position the ICD to provide an adequate sensed R-wave and acceptable high-voltage impedance. After the DFT testing, we checked the intra-cardiac recordings to identify any undetected events during the testing and to confirm any association between the undetection of VF events and any delay in the ICD discharge. All DFT testing was performed with electrocardiographic monitoring and the full resources for cardiopulmonary resuscitation under deep sedation using thiopental. Before the patients were discharged, the device was programmed with the first shock power set at the DFT plus a 10J margin with a direct biphasic waveform from the can to the RV coil. The tachycardia detection zone was programmed according to the previously documented events for the secondary prevention patients. Patients were seen in the follow-up clinic at 4-month intervals after the implantation. Clinical and device interrogation evaluations were carried out at each follow-up visit. Physicians were encouraged to follow the current practice guidelines for pharmacologic therapy if the patients were taking any medications, depending on their clinical status.

Definition and study endpoints: A high DFT was defined as exhibiting less than a 10J safety margin between the DFT and the maximum energy output of the implanted device. In the present study, major adverse cardiac events (MACE) included appropriate shocks from an antitachycardia pacing (ATP) for any ventricular arrhythmias, heart failure admission, and any other cardiovascular events. The study endpoints included any MACE and cause of death (clinical outcomes).

Statistical analysis: The data are presented as the mean ± SD or counts (%). Categorical data were compared with the chi-squared test or Fisher's exact test when cell values were less than 5. Continuous data were compared using a two-tailed, unpaired t-test. A probability value of <0.05 was considered statistically significant. Survival curves were calculated by the Kaplan-Meier method, and comparisons between the two groups of patients were performed with the log-rank test. The best subset regression model was used to identify any significant variables for inclusion in the multivariate regression model and to find the parameters associated with the predictive factors predisposing to the endpoints. JMP™ 11 software (SAS Institute Inc, Cary, NC, USA) was used for all statistical analyses.

Results

The demographic clinical characteristics of the 81 patients with DFT testing during the ICD implantation are shown in Table I. The mean age of the patients at implant was 64.6 ± 13.8 years (range 21-84years), the majority were male (66 pts, 81.5%), and the mean left ventricular ejection fraction (LVEF) was 43 ± 19.5%. The underlying heart disease included ischemic cardiomyopathy in 32 patients (39.5%), dilated or hypertrophic cardiomyopathy in 18 (22.2%), idiopathic ventricular arrhythmias in 15 (18.5%), Brugada syndrome in 10 (12.3%), and other underlying conditions in 6 (7.4%). Thirty-three patients (40.7%) had a primary prevention indication for implanting the ICD. Documented co-morbidities included hypertension in 54 patients (66.7%), diabetes in 14 (17.3%), renal disease (eGFR < 60 mL/m^2) in 31 (38.3%), and atrial fibrillation (AF) in 24 (29.6%). According to the procedural indexing, 48 patients (59.3%) underwent a first implantation, 31 (38.3%) a generator exchange, and 2 (2.4%) a system revision or system upgrade. A single chamber ICD (VR) was implanted in 39 patients (48.1%), and a CRT-D device in 23 (28.4%). The generators used according to the manufacturer were a Boston Scientific device

Table II. Patients' Characteristics by Non-High DFT and High DFT Group

Variable	Non-high DFT (n = 70 (%))	High DFT (n = 11 (%))	P
Age (years)	64.4 ± 14.1	65.7 ± 12.9	0.6
Male (%)	55 (78.6%)	11 (100%)	0.08
BMI (kg/m^2)	22.7 ± 4.07	23 ± 3.83	0.84
De novo implantation	42 (60%)	6 (54.5%)	0.83
Diabetes	14 (20%)	0 (0%)	0.10
Hypertension	46 (65.7%)	8 (72.76%)	0.64
Atrial Fibrillation	17 (24.2%)	7 (63.6%)	0.007
eGFR (mL/minute/1.73 m^2)	66.1 ± 28.1	67.2 ± 42.7	0.91
LVEF (%)	44.4 ± 19.2	34.8 ± 20.2	0.12
Amiodarone usage	30 (42.8%)	6 (54.5%)	0.58
Ischemic cardiomyopathy	28 (40%)	4 (36.3%)	0.88
LVDd (mm)	55.7 ± 12.6	59.8 ± 13.8	0.34

BMI indicates body mass index; LVEF, left ventricular ejection fraction, eGFR, estimated glomerular filtration rate (mL/minute/1.73 m^2), and LVDd, left ventricular diastolic dimension.

Table III. Patients' Characteristics by Study Endpoint (n = 81)

Variable	Mean ± SD or n	Event group (n = 22 (%))	Event Free Group (n = 59 (%))	P
Age (years)	64.6 ± 13.8	69.1 ± 8.62	62.9 ± 15.1	0.07
Men	66	19 (86.4)	47 (79.7)	0.48
LVEF (%)	43 ± 19.5	31.1 ± 16.7	47.5 ± 18.8	< 0.001
LVEF ≤ 35%	34	14 (63.6)	20 (33.9)	0.016
eGFR (mL/minute/1.73 m^2)	66.3 ± 30.2	54.7 ± 30.6	70.7 ± 29.1	0.034
eGFR < 60 (mL/minute/1.73 m^2)	31	11 (50)	20 (33.9)	0.20
Ischemic cardiomyopathy	32	10 (45.5)	22 (37.3)	0.50
Amiodarone usage	36	11 (50)	25 (42.3)	0.53
β-blocker usage	50	17 (77.2)	33 (55.9)	0.07
Atrial fibrillation	24	12 (54.5)	12 (20.3)	0.0035
Diabetes	14	4 (18.1)	10 (16.9)	0.89
Hypertension	54	18 (81.8)	36 (61.0)	0.06
DFT (J)	11.6 ± 9.24	17.4 ± 12.6	9.5 ± 6.5	< 0.001
High DFT	11	7 (31.8)	4 (6.78)	0.0034
ICD type (Single chamber)	39	9 (40.9)	30 (50.8)	0.42

LVEF indicates left ventricular ejection fraction; eGFR, estimated glomerular filtration rate (mL/minute/1.73 m^2); ICD, implantable cardioverter defibrillator, and DFT, defibrillation threshold.

(Boston Scientific, Marlborough, Massachusetts, USA) in 31 patients (38.3%), Medtronic device (Medtronic Inc., Minneapolis, Minnesota, USA) in 20 (24.7%), St. Jude Medical device (St. Jude Medical Inc. St. Paul, Minnesota, USA) in 14 (17.3%), Sorin device (Sorin Group S.p.A Milan, Italy) in 13 (16%), and Biotronik (Biotronik SE & Co.KG, Berlin, Germany) in 3 (3.7%).

During the DFT testing, all patients were induced VF utilizing with a low energy T-wave shock or a high-frequency burst method. The first shock was given at a protocol-specified energy of 5J in all patients. In 40 patients (49.4%), the VF was terminated by the first shock without any delay during the DFT testing. In 30 patients (37%), the VF was terminated by the second shock (10-20 J), and in 11 patients, the VF was terminated by the third shock (25J<). In all patients, the induced VF was terminated using the ICD. As a result, the mean DFT was 11.6 ± 9.24J in the entire group and 11 patients (13.6%) had a high DFT. Compared to the high DFT and non-high DFT group, the rates of atrial fibrillation (AF) was significantly higher in the high DFT group (63.6% versus 24.2%, P = 0.007) (Table II). Five patients exhibited high DFT but were not *de novo* implantation cases, 2 patients had a history of appropriate shock (including 1 ATP), and one patient had a prior history of heart failure admission.

During the follow-up period (median 432 days; range from 151days to 1146 days), all patients could be monitored and no one was lost to follow-up. Three patients (3.7%) died from unrelated causes (pancreatic cancer, interstitial pneumoniae, renal failure), 11 were (13.6%) admitted for heart failure, and in 8 ventricular tachyarrhythmic events (9.9%) with appropriate shocks (including one with anti-tachycardia pacing) were recorded, respectively. In the patients with ventricular tachyarrhythmic events, all arrhythmias were terminated upon the first shock. As shown in Table III, the patients with clinical events had a significantly lower LVEF (P < 0.001), lower estimated glomerular filtration rate (eGFR) (P = 0.034), greater occurrence of AF (P = 0.035), and a higher DFT (P < 0.001) as compared to the event-free group. In order to

identify the predictors of the study endpoint, a logistic regression analysis was performed. The presence of AF, a high DFT, and an LVEF ≤ 35% were related to clinical events in terms of a *P*-value < 0.2 by a univariate analysis. A multivariate analysis identified that only a high DFT was an independent predictor for the study endpoint (OR 4.54, CI 1.03-21.9, $P = 0.045$; Table IV). As shown in the Figure, a Kaplan-Meier survival analysis showed a significant difference in the study endpoints between the two groups (Log-rank $P = 0.0069$; Figure).

Discussion

The present study is summarized by the following points: 1) The mean DFT was 11.6 ± 9.24J and 11 patients (13.6%) had a high DFT with modern devices. Surprisingly, in 40 patients (49.4%), the VF was terminated upon the first shock (5J) without any delay during the DFT testing. 2) The rates of AF was significantly higher in the high DFT group (63.6% versus 24.2%, $P = 0.007$). 3) During the follow-up period (median 432 days; range from 151 days to 1146 days), the incidence of clinical events, which included MACE and any cause of death, occurred in 22 patients (27.2%). In the multivariate analysis, a high DFT was the only predictive factor for the incidence of the clinical outcome (OR 4.54, 95% CI 1.03-21.9, $P = 0.045$).

DFT testing is often performed at the time of an ICD implantation by purposefully inducing VF to establish an effective arrhythmia detection and termination. However, some criticism of DFT testing has arisen because of the lack of data showing the efficacy and benefit.

Table IV. Multivariate Analysis of Predictive Factors for the Clinical Events

Variable	OR	95%CI	*P*
LVEF ≤ 35%	2.82	0.93-8.91	0.064
Atrial fibrillation	3.04	0.95-9.67	0.059
High DFT	4.54	1.03-21.9	0.045

To answer these questions, the results of two randomized prospective trials evaluating intraoperative DFT testing were presented recently.[10,12] The SIMPLE trial is a single blind, randomized, multicenter trial, evaluating the non-inferiority of non-testing versus testing using a composite outcome of arrhythmic death or failed appropriate shocks for ventricular arrhythmias. From its study, the authors concluded that routine DFT testing at the time of the ICD implantation is generally well tolerated but does not improve the shock efficacy or reduce the arrhythmic death. Also in the NORDIC ICD trial, they concluded that DFT testing during the first ICD implantation should no longer be recommended for routine left-sided ICD implantations. However, both of the trials did not include a large number of patients already implanted with an ICD system and that fact may have lead to the opposing opinion that intraoperative DFT testing might still be recommended.[11]

In clinical practice, if the DFT testing is not performed, devices are usually programmed to the maximum energy for VF termination. However, previous clinical and pre-clinical studies showed that the ICD shocks may induce myocardial injury and shocks with a higher output can cause more severe myocardial damage than those with a lower output.[13-15] If the DFT testing is not performed, it is hard to be convinced that the lower energy output would work effectively. In the present study, we found that the mean DFT was 11.6 ± 9.24J using modern era devices that performed the measurements with step-by-step DFT testing, and in almost half of the study patients (49.4%), the VF was terminated by a low energy (5J). These data should be considered when we program the modern era ICD devices. Also, our study suggested, DFT testing might be one alternative for patients to set a lower power output in order to reduce myocardial damage. Of course, these results should be confirmed with large and well-designed prospective, randomized trials.

In the present study, we found that AF was signifi-

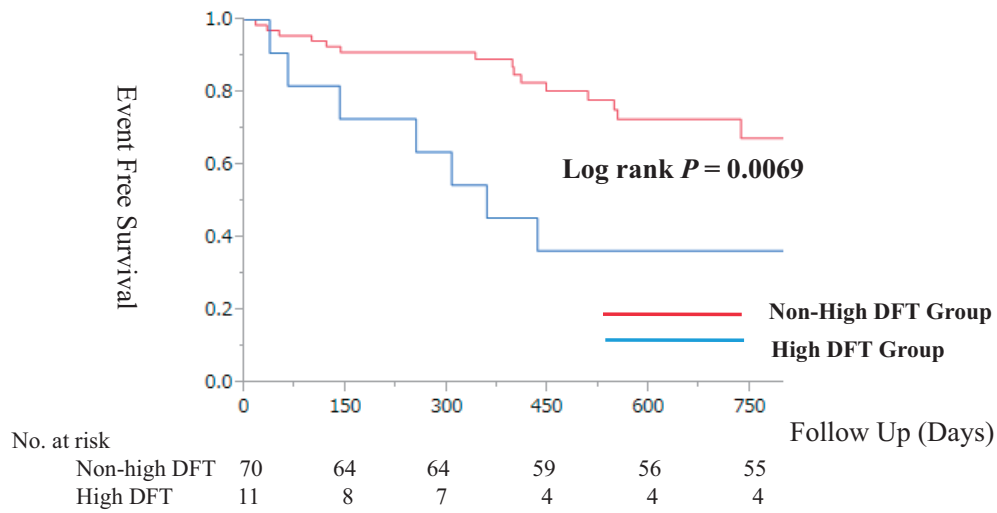

Figure. Kaplan-Meier survival curve showing the study endpoint (major adverse cardiac events and any cause of death) by the DFT category. Blue solid line indicates high DFT group; and red solid line, non-high DFT group.

cantly higher in the high DFT group (63.6% versus 24.2%, $P = 0.007$). Previous studies have reported the characteristics of high DFT patients and their predictors included the presence of AF, HT, low left ventricular ejection fraction (LVEF), increase in left ventricular (LV) diameter, and use of amiodarone.[16-18] In contrast to previous studies, we could not find the significant difference between the high DFT and non-high DFT groups. This is because the present study included a smaller number of patients compared to previous studies, and the difference may not be statistically significant. In addition, the rate of patients with preserved LVEF, such as idiopathic VF, Brugada syndrome was relatively high in our study. In this regard, the mean LVEF was relatively higher than in past studies.[17,18] The heterogeneous patient population in our study could have negated the possible involvement of LVEF as a predictor of high DFT.

There are limited data on the prognostic significance of an elevated DFT. Early data has suggested that some deaths in ICD patients occur mostly in those with high DFTs.[19,20] Rubenstein, *et al*. demonstrated that an elevated DFT is a significant independent predictor of the overall mortality and DFT provides incremental information about the mortality and prognosis. Further, they also showed that an elevated DFT is associated with increased mortality even in the setting of an adequate safety margin.[20]

Compared to that study,[20] our patients were implanted with relatively new devices (patient enrollment, October 1995 to June 2000 versus January 2012 to January 2015), including CRT devices, and fewer patients had ischemic cardiomyopathy (54.3% versus 39.5%). Taken together, regardless of the device type or underlying heart disease, a high DFT may predict a worse prognosis in recipients of ICDs. Although it is not clear whether an elevated DFT increases the mortality by rendering the ICD less effective or an elevated DFT is simply a marker for a poor prognosis, if the patients have DFT testing and a high DFT, these patients will require good care in our clinical practice.

Study limitation: This study included several limitations. First, the major limitation of the present study was the small sample size to ensure the results and the induced VT/VF was different from spontaneously VT/VF. However, the actual DFT measured by the step-by-step DFT testing with modern devices was unique and evaluations of the relationship between the clinical outcome and DFT are limited. Second, this was a retrospective study in a single center and may therefore have incorporated important biases, especially, the number of high DFT patients. Third, although a current trend toward the omission of intraoperative DFT testing at the time of new implantations of ICDs is supported by the two randomized trials, we included 48 patients (59.3%) who were implanted with new ICDs. This was due to the study results shown after our patient enrollment. Fourth, because the follow-up period of this study was widely varied (median 432 days; ranged from 151 days to 1146 days), the incidence of clinical events may be different from the follow-up period.

Conclusion

The mean DFT with modern devices was 11.6 ± 9.24 J, and high DFT patients were identified in 13.6% of the ICD recipients. A high DFT predicted the incidence of clinical events after the ICD implantation.

Disclosures

Conflicts of interest: None.

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