

Implantable Cardioverter Defibrillator with and without Defibrillation Threshold Testing

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ABSTRACT: **Background:** Defibrillation threshold (DFT) testing at the time of implantable cardioverter defibrillator (ICD) insertion is performed routinely. This practice is being reconsidered due to doubts about its ability to improve ICD efficacy and evidence that survival may not be affected by the test.

Objectives: To compare the outcome of ICD recipients who underwent DFT testing and those who did not.

Methods: A total of 213 eligible patients were implanted with an ICD between 2004 and 2009. DFT testing was performed in 80 of them. We compared total mortality, appropriate and inappropriate ICD shocks, and anti-tachycardia pacing (ATP) events between DFT and non-DFT patients during a follow-up of 2 years.

Results: On comparing the DFT and non-DFT groups, we found a 2 year mortality rate of 7.5% versus 8.3%, respectively ($P = 0.8$). Furthermore, 20.7% of patients in the DFT group and 12.4% in the non-DFT group had at least one episode of ICD shock ($P = 0.15$). With regard to ICD treatment (ICD shocks or ATP events), 57.7% in the DFT group and 64.2% in the non-DFT group received appropriate treatments ($P = 0.78$).

Conclusions: No significant differences in the incidence of 2 year mortality or percentage of ICD treatment emerged between the DFT and non-DFT groups.

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KEY WORDS: defibrillation threshold (DFT), implantable cardioverter defibrillator (ICD), anti-tachycardia pacing (ATP), sudden death, ventricular fibrillation (VF), ventricular tachycardia (VT)

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Implantable cardioverter defibrillator represents the standard of care for patients at high risk of sudden cardiac death [1]. ICD has improved absolute survival when implanted for primary or secondary prevention [1,2].

Defibrillation threshold testing at the time of ICD implantation is traditionally considered an implant criterion by which

ICD = implantable cardioverter defibrillator

a “safety margin” for defibrillation is tested with the chosen lead configuration [3]. Publications of recent years question whether the information obtained from the DFT test is worth the risk of the test itself; this is especially true in an era of technological advancement with highly efficient ICD devices [4,5].

There is evidence that DFT testing may not reproduce the natural conditions of ventricular arrhythmias (congestive heart failure exacerbation, ischemia, electrolyte impairment) and therefore may not constitute a good predictor of outcome [6,7]. In addition, low DFT does not guarantee a successful defibrillation in the case of a spontaneous ventricular fibrillation; similarly, a high DFT is not always accompanied by a worse prognosis [8,9]. It has been shown that DFT testing is not free of complications during the procedure or afterwards [10-13]. Moreover, long-term survival and efficacy of ICD treatment may not necessarily be affected by DFT testing [7,14-17].

PATIENTS AND METHODS

We performed a retrospective cohort analysis of 278 consecutive patients who were treated with an ICD for the primary and secondary prevention of sudden cardiac death at our institution between January 2004 and July 2009. Of them, 213 patients were followed for at least 2 years and they constituted our study cohort. Two groups were compared, those who underwent DFT testing during ICD implantation and those who did not.

DFT was defined as the shock able to successfully revert an inducible ventricular fibrillation with at least 10 joules below the maximal energy of the ICD capacity. The decision whether or not to perform DFT testing depended on the operator's preference.

Data on ICD-9 diagnoses, procedure details, and follow-up in the pacemaker clinic were obtained from the hospital database. After the implantation patients were examined in our department every 3 to 6 months or after ICD therapies or syncope events. At every follow-up visit the devices were interrogated, and arrhythmic events, ICD shocks and anti-tachycardia pacing events, appropriate or inappropriate, were analyzed. Due to ethical considerations implanted devices were not interrogated after the patient's death.

DFT = defibrillation threshold

We compared all-cause mortality and episodes of ICD shocks or ATP events between the two study groups during a follow-up period of 24 months. The study was approved by the Institutional Review Board.

The results are presented as the mean \pm standard deviation for continuous variables and as the percentage of the total number of patients for categorical data. Student's *t*-test was used for comparison of the continuous variables and chi-square test for categorical data with the use of Fisher's exact test as needed. Mann-Whitney test was used for comparison of continuous variables with abnormal distribution. Survival curves were calculated by the Kaplan-Meier method and comparison between the two groups of patients was performed by log-rank test. A two-sided *P* value < 0.05 was considered statistically significant. Data summaries were performed using the Statistical Package for Social Sciences (SPSS, Chicago Inc.) for Windows, version 16.0.

RESULTS

Of the 213 patients, 80 underwent DFT testing at the time of ICD implantation and 133 did not. The clinical characteristics of the patients are shown in Table 1. No DFT testing complications were observed, neither clinical nor ICD-related.

Patients who underwent DFT testing were younger than those who did not (mean age 61.8 ± 14.6 vs. 66.9 ± 12.9 , *P* = 0.01). There were no significant differences between groups regarding gender or primary and secondary prevention.

Outcomes of the study are shown in Table 2. One year after ICD implantation four fatal events occurred in the DFT group and eight in the non-DFT group, a rate of 5% vs. 6% respectively (*P* = 0.7). During the 24 month follow-up of the entire cohort, 6 fatal events were registered in the DFT group and 11 in the non-DFT group, a rate of 7.5% vs. 8.3% respectively (log-rank test, *P* = 0.8) [Figure 1].

There were no significant differences in the number of ICD shocks (20.7% vs. 12.4%, *P* = 0.15) and ATP events (18.3% vs. 15.3%, *P* = 0.7) between the groups, respectively. Moreover, there were no significant differences in the comparison of episodes of appropriate ICD shocks or ATP events (57.7% vs. 64.7%, *P* = 0.78) respectively between the two study groups.

During the follow-up no patient required modifications of defibrillation output or electrode repositioning, manipulation or replacement due to failure to successfully terminate a monomorphic ventricular tachycardia.

DISCUSSION

For the last two decades technological improvement in the safety and performance of ICD devices eliminated the need for further testing of patients before discharge from hospital [7].

ATP = anti-tachycardia pacing

Table 1. Clinical characteristics of patients

	DFT group (n=80) n=82	Non-DFT group (n=133)	<i>P</i> value
Age (yrs)	61.8 \pm 14.6	66.9 \pm 12.9	0.01
Men	73 (91.3)	112 (84.2)	0.2
Left side implantation	76 (95)	128 (96.2)	0.7
Left ventricular ejection fraction (%)*	29.4 \pm 5.2	28.8 \pm 4.9	0.4
Single chamber	50 (62.5)	67 (50.4)	0.085
Dual chamber	16 (20)	36 (27.1)	0.3
Cardiac resynchronization therapy defibrillator	14 (17.5)	29 (21.8)	0.3
Primary prevention	33 (41.3)	58 (43.6)	0.8
Secondary prevention	47 (58.8)	75 (56.4)	0.8
Ischemic cardiomyopathy	66 (82.5)	101 (75.9)	0.3
Non-ischemic cardiomyopathy	14 (17.5)	30 (21.9)	0.2
Others**	4 (5)	2 (1.5)	0.051
Heart failure	54 (67.5)	95 (71.4)	0.6

Values are given as (%) or as mean \pm SD

*At the time of implantation

**Brugada syndrome, hypertrophic obstructive cardiomyopathy, long QT syndrome

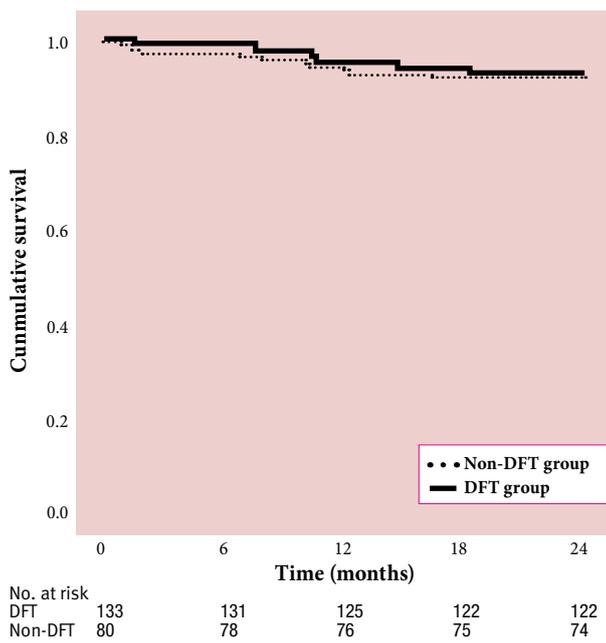
Table 2. Patient outcomes

	DFT group (n=80)	Non-DFT group (n=133)	<i>P</i> value
Two year mortality	6 (7.5)	11 (8.3)	0.8
One year mortality	4 (5.0)	8 (6.0)	0.7
ICD shock	17 (21.3)	17 (12.8)	0.1
ATP episodes	15 (18.8)	21 (15.3)	0.7
Appropriate ICD shock or ATP	15 (57.7)	22 (64.7)	0.78

Values given are n (%)

Today, although in abbreviated form, we still check the performance and safety of devices at implantation with DFT testing despite having no evidence that this procedure improves patient outcome; in fact there is accumulating evidence that this testing examination may indeed be unsafe [10-13]. The fact that defibrillation is a probabilistic phenomenon, a shock that cannot reverse an arrhythmia in the first attempt but could do so with the same amount of energy in the second attempt, further complicates the interpretation of DFT testing results.

Figure 1. Kaplan-Meier plots for 2 year survival stratified by DFT



It is also noteworthy that there are no recommended guidelines for performing DFT testing and that the test is still being performed as a type of “common practice” protocol. Consequently, different centers have adopted a variety of protocols, and operators even within the same institution may choose not to perform it at all. Intuitively, the tendency is to perform DFT testing to check the integrity and proper functioning of the implanted device. However, the very small chance of diagnosing a high DFT, an even smaller chance that the device will fail to revert a real-time arrhythmia despite a high DFT, and the chance that the test itself will result in complications such as hemodynamic instability, stroke or non-responding ventricular fibrillation, argue against performing it [18]. Viskin and Rosso [7] noted that DFT testing may not reproduce the natural conditions of ventricular arrhythmias and, therefore, the results of DFT testing may not constitute a good predictor of outcome.

It is assumed that simplifying the implantation procedure by not performing DFT testing may reduce the risk of hemodynamic instability, stroke and other complications related to the test itself. In a study of 19,067 patients who underwent ICD implantation, Birnie et al. [10] registered 3 DFT testing-related deaths, 5 DFT testing-related strokes, and 27 episodes that required prolonged resuscitation secondary to DFT testing. Furthermore, long-term survival may not necessarily be affected by DFT testing [15-17].

Calvi et al. [17] showed no significant efficacy advantage after 1 year follow-up in patients tested at the time of implantation versus untested patients. These findings agree with those of Bianchi and co-researchers [16], who found no significant differences in total mortality, cardiovascular mortality, sudden cardiac death or spontaneous episodes of ventricular arrhythmia between the two groups during a 2 year follow-up.

Our study findings add to the growing evidence that DFT testing may not contribute to a better performance of ICD therapy. In our experience, whether or not DFT testing is performed at the time of implantation has no effect on the mortality rate or on the efficacy of ICD treatment (appropriate vs. inappropriate ICD shocks or ATP events).

The real challenge for clinicians lies in identifying those patients at risk of having a high DFT before the implantation procedure and reserving DFT testing for them only [7,19,20]. Approximately 5% of patients have a high DFT and theoretically this is the population of patients at high risk of sudden cardiac death due to unsuccessful defibrillation [4,21-23]. Performing DFT testing in every patient treated with an ICD would seem to lead ideally to the identification of these 5% of patients [24]. It is estimated that performing DFT testing in all patients will lead to a reduction in mortality of about 0.4% in patients treated for primary prevention of sudden cardiac death and 0.35% in those treated for secondary prevention [24]. On the other hand, the risks of the test itself, according to Brignole and co-workers [11] and Birnie et al. [10], are 0.07% and 0.016% respectively for mortality, and 0.4% and 0.17% respectively for life-threatening complications.

Therefore, it can be assumed that the risk of the test itself is similar to the decrease in mortality achieved when the test is performed in all patients [24]. Ultimately, in an era of technological advancement with high-output ICDs and where most events are terminated by ATP, performing DFT testing seems more dangerous than not performing it [24].

Limitations of this study include its retrospective nature and lack of randomization, the relatively small number of patients, and the small number of endpoints. DFT-tested patients were significantly younger than those in whom DFT testing was not performed, probably because of higher comorbidity rates in older patients that could increase the risk of DFT testing.

CONCLUSIONS

No differences in overall mortality or in the percentage of ICD treatment were seen between ICD patients tested for DFT at the time of implantation vs. patients in whom no testing was performed. These results should be confirmed in a larger prospective randomized trial.

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Capsule

New discovery could yield MS cure

Researchers studying diabetic mice have made leaps towards a cure for multiple sclerosis (MS). The Tel Aviv University team found that when mice with type 1 diabetes are injected with myelin protein they experience periods of relapse and remitting disability associated with brain lesions in humans who have MS. For the first time scientists have been able to monitor this brain lesion process using magnetic resonance imaging. It is believed that the discovery will lead to more effective treatments for MS and,

with advances continuing to be made in MS research, that the condition will one day be controllable – like HIV/AIDS. Recent studies have identified about 20 genes associated with the development of MS and it is estimated that in the next two years there will be around 80 associated genes that will provide an accurate picture of the disease's genetic basis. Once this is achieved, development treatments for MS will be far simpler and effective.

Israel High Tech & Investment Report

What I am remains to be proved by the good I do

Mary Baker Eddy (1821-1910), founder of Christian Science, a Protestant American system of religious thought