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Defibrillator Threshold Testing

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1. Introduction

Since implantable cardioverter-defibrillators (ICDs) were first introduced, defibrillator threshold (DFT) testing was considered an integral part of the implant procedure. Performing DFT testing verifies the ability of the ICD in detecting and aborting the lethal arrhythmia it was designed to treat. The process has evolved with the development of the ICD's and the expanding indications for their usage. Recent studies even questioned the need for DFT assessment. Currently this matter is controversial with no firm guidelines. In this chapter we present the basic information on DFT testing, how to manage high DFT, and then discuss the evidence for and against performing the test.

2. DFT concept

DFT testing is performed by inducing ventricular arrhythmia and then finding the minimal amount of energy delivered by the ICD to defibrillate the myocardium back to sinus rhythm. Central to the concept of determining the DFT, was the discovery since 1930, that electrical shocks themselves can induce ventricular fibrillation (VF) [1]. By giving a shock during the vulnerable period of repolarization, VF could be reproducibly induced. Ventricular tachycardia (VT) may also be induced, but in a relatively small percentage of patients [2]. As the amount of energy delivered during the vulnerable period is increased, a threshold is reached that does not induce VF [3]. This is called the upper limit of vulnerability (ULV) and is proportional to DFT value [4-5]. This concept can be used as a surrogate for DFT [6-7]. Instead of inducing VF and checking the threshold at which it terminates, a different protocol is used that delivers variable strengths of shocks during the vulnerable T-wave phase and then establishes ULV. As compared to regular DFT test, ULV test is done during sinus

rhythm and not during VF. Using this approach there is a need for more number of shocks, but less number of times that VF are induced.

The threshold to terminate ventricular fibrillation with ICD's is usually in the 5 to 30 J range. It was the ability to reduce the energy requirements by 10 folds as compared to external defibrillator that made the ICD a reality [8]. Otherwise the size of the ICD would have to be much bigger to store the needed energy for defibrillation. Although the threshold is expressed in relation to the energy discharged by the ICD, in reality it is the voltage and its duration that is the critical factor in defibrillation [9-10]. Duration has a relatively narrow range to be effective (in the range of few milliseconds). To achieve this precise phase duration of defibrillation, the capacitor discharge is truncated in either a tilt based formula which truncates the discharge after a certain percentage of decay in the voltage has been reached, or more simply in a time based manner after a certain time has elapsed. Voltage is usually in the hundreds of volts range. If voltage is too low it may induce rather than terminate fibrillation as explained earlier. High voltage (above 1000 Volts) is also not without its risks, as it may result in stunning of the myocardium and subsequent electromechanical dissociation [11-12]. The voltage wave form can be manipulated to make defibrillation more effective and therefore require less energy. Biphasic wave, which is the standard now in ICD's, has reversal of the initial polarity. The initial wave results in charging of the cell membrane as a result of the voltage gradient. The reversal which is termed "burping" is theorized to absorb the initial energy and therefore avoid proarrhythmia [11-12]. The biphasic wave form can be manipulated by changing the initial voltage, and by changing the duration and the ratio of its waves. Different manufactures use different formulas in their devices, and some allow changing of the parameters by the electrophysiologists in case of high DFT.

3. Performing DFT testing

Before doing DFT testing, consent should be taken from the patient explaining the risk and benefit of the procedure. Vital signs should be stable and basic lab results such as electrolytes should be within normal range. There should be no contraindication to performing the test such as severe aortic stenosis or intracavitary thrombus. An external defibrillator should be placed ready next to the patient, preferably with defibrillator patches attached to the patient. As the shock is painful, adequate sedation or short anesthesia should be given with careful monitoring of vital signs and saturation level [14].

After the device is implanted good lead position should be verified by X-ray. The lead is tested to ensure adequate sensing and pacing thresholds and normal impedance values.

Prior to VF induction, the device is activated and programmed with the amount of energy to be delivered. Ventricular fibrillation is usually induced via the device. There are several methods of VF induction such as programmed ventricular stimulation, T wave shock, fast burst pacing, or by applying low voltage direct current [15]. Following VF induction the patient is monitored carefully until the device detects the arrhythmia and restores it back to sinus rhythm. If the device fails, external defibrillation should be immediately performed.

To find the exact DFT value, this process has to be repeated several times with either a step up, step down, or a binary fashion until DFT or ULV are found [16-17]. Although the term threshold should indicate a value above which defibrillation is successful and below which shocks fail, in reality DFT is a probabilistic phenomenon with a certain percentage of success rate [17-18]. One shock may be successful while a successive one with the same conditions may fail [5]. Despite the poor reproducibility of DFT, it is still a useful parameter, as this value taken with a safety margin above it, gives a high clinical success of VF termination. The standard safety margin is 10 J, although 5 J may be enough [19-20].

DFT testing with several shocks and titrations may be useful in a research protocol, where the exact value has important clinical significance. A simpler, yet safe approach is the defibrillator safety margin (DSM) test [21]. In this method, a single or two VF inductions may be enough. The device is usually programmed to a value that is expected to restore sinus rhythm following induction. This value depends on the operator preference. It is usually an average value that is at least 10 J below the maximum output of the device [22]. If it is successful, then this value should at least be equal to the DFT value. If the shock fails, then step up approach has to be used to find the threshold.

Study	Year	N	Percent
Kelly et al [23]	1988	94	5.3%
Winkle et al [24]	1989	270	2.6%
Pinski et al [25]	1991	125	18%
Epstein et al [26]	1992	1946	4.6%
Gold et al [27]	1997	114	8%
Brodsky et al [28]	1999	764	3.1%
Shukla et al [29]	2003	968	11%
Russo et al [30]	2005	1139	6.2%
Theuns et al [31]	2005	127	14%
Mainigi et al [32]	2006	121	12%
Guenther et al [33]	2012	975	1.4%
Cheng et al [34]	2012	243	5.3%

Table 1. Incidence of high DFT

High DFT, defined in most studies as a threshold of < 10 J below the maximum output of the device, is estimated to occur in about 5% of ICD implants (range 1.4 to 18%) (Tables 1) [23-33]. Although the exact value of DFT cannot be predicted in an individual patient prior to testing, there are some clinical parameters associated with increased thresholds (Table 2) [27-29,32-35].

Young age
Low ejection fraction
Hypertrophic cardiomyopathy
Non coronary artery disease
Medications (specially amiodarone)
Larger and small left ventricular sizes
Large body size
Prolonged QRS duration

Table 2. Clinical factors associated with high DFT 's

DFT testing is usually performed introperatively at the time of implant before the pocket is closed to allow intervention in case of high thresholds. Sometimes it is done at the time of discharge or at a later time when the lead has assumed a stable position [28,36].

4. Management of high DFT

If a patient is found to have elevated thresholds, the initial step is to verify that this is not caused by a reversible problem related to the implant procedure itself (table 3). If no reversible cause is found, then there are several options available. These are classified into non-invasive and invasive methods (table 4).

Hypotension
Pneumothorax
Pericardial effusion
Large pleural effusion
Pulmonary edema
Sedation related such as aspiration and hypoxia
Acidosis
Electrolyte imbalance
Medications
Ischemia
Prolonged procedure
Lead dislodgment

Table 3. Reversible causes of high DFT

Adjustment to improve DFT	Comment
Non Invasive	
Medications [37-41]	Particularly amiodarone has been shown to increase thresholds. Medications that potentially decrease thresholds include sotalol and dofetilide.
Lead Polarity [43-44]	The RV lead is the anode (positive) vector. It may be changed to cathode (negative).
Vector of defibrillation [41,45]	Adding an SVC coil is most effective when a single coil has high resistance of > 58 ohm. If dual coil system is implanted, the vector can be changed electronically.
Wave form [41,46]	Change of Tilt and phase duration of shocks is available in some devices and may be optimized individually.
Invasive	
Lead repositioning [47-48]	Apical position has lower DFT when compared to a proximal position. Septal and RVOT positions may have lower thresholds
Addition of extra leads to change the vector of the shock [49-51].	Subcutaneous array, coronary sinus and azygous vein leads could be introduced to lower thresholds
Upgrading to higher output device	

Table 4. Approaches to improve DFT

Changing or stopping a medication associated with high threshold may help the problem [37]. Amiodarone has been particularly quoted in the literature as causing high thresholds [38]. Other possible medications include lidocaine and verapamil. On the other hand, medications that do not affect or potentially reduce DFT include sotalol, dofetilide, beta-blocker and dronedarone [37-40].

There are some programmable parameters in the ICD that can affect DFT. These include polarity of the lead, the vector of defibrillation, and the tilt and duration of the shock wave [41-42]. The lead is configured with an anodal (positive) distal coil. This configuration results in an average reduction of 15% in DFT as compared to a cathodal right ventricular (RV) coil [43]. Reversing it to cathode results in the energy propagating away from the lead instead of “collapsing” towards it. This is theorized to increase the arrhythmia potential. However, changing polarity has been shown to decrease DFT in some of the patients and this configuration can therefore be attempted [44].

A dual-coil, active pectoral lead system is the most commonly used configuration. A proximal coil placed in the superior vena cava (SVC) area has been found to decrease DFT as compared to a single coil system [41,45]. This effect is particularly effective when the single coil resistance is high (above 58 ohm), while the effect on the threshold is mixed with low single coil resistance. Control of proximal coil can be done electronically in a dual coil lead. Addition of an SVC coil might be considered in patients with single coil and high resistance.

The proximal coil location should be in the high SVC and brachiocephalic area rather than the low SVC and atrial area as the later is associated with higher DFT value [45].

The phase duration of defibrillation is critical in achieving sinus rhythm [9-10]. The optimal phase duration is not exactly known and it can be optimized in some devices for individual patients with high DFT's [46].

Changing a nominal parameter should not be taken lightly, as these are the ones tested and proven with clinical research. Any adjustment made to the settings should be verified by repeated induction and the reassurance of a successful defibrillation.

Several invasive choices that reduce DFT are available. Changing the RV lead location may reduce DFT. The standard RV position is the RV apex. This has the advantage of a stable position and good threshold. Alternative lead positions that have good thresholds are the right ventricular outflow tract (RVOT) and the septum. An active fixation system should be used in these areas. A right free wall position has the highest DFT [47-48]. Changing the shock vector may lower DFT. This can be achieved by incorporating subcutaneous array or an additional lead in the azygous vein or the coronary sinus [49-51]. Upgrading to higher output devices may be useful in patients with borderline elevated thresholds.

5. The arguments for and against performing DFT testing

Since implanting ICD's in the early 1980's, VF induction and testing the device ability to restore sinus rhythm not only helped in determining DFT's, but also allowed testing of the sensing capability of the device, the ability of the programmed algorithm to recognize the arrhythmia, and the ability of the capacitors to deliver the stored energy. This was an important step in testing a new device that is designed to treat a lethal arrhythmia. Patients who were found to have high threshold had intervention performed to attempt to lower the DFT's. If the thresholds could not be lowered then many physicians did not implant the device. This was because of the concern that a shock might change a stable VT into VF and then not be able to terminate it. There were several reports of increased mortality in patients with high DFT and case reports of deaths due to failed defibrillation. [23,28,52-54] (table 5). Intuitively, finding DFT will result in reduced mortality as it allows the recognition of patients who will not respond to the shock and therefore find a subgroup of patients who need further intervention. However, this matter is not so simple.

Testing involves induction of ventricular fibrillation in patients with significant heart disease with a potential for morbidity and mortality. Complications associated with DFT testing include worsening heart failure, hemodynamic compromise, cerebrovascular accidents and even deaths. In the Canadian Experience study by Bernie et al which looked at 19,067 patients, thirty five patients (0.18%) had serious complications [61]. The recognition of the complications was coupled with improvements in the lead and defibrillator technology. In addition, ICD use expanded considerably after studies showed its benefit not only in secondary but also in primary prevention of sudden death. This changed the risk benefit ratio of

DFT testing. Several studies gradually emerged that questioned the need to find DFT (table 5). This lack of benefit of DFT testing shown in several studies may be explained by several factors:

- The comparison of the mortality in patients who had DFT testing versus those who did not have a test may be biased by excluding unstable patients from DFT testing and including them in the non tested group.
- The comparison should include the morbidity and mortality associated with the test itself and also the problems related to the intervention to reduce DFT. Even simple measures such as changing a medication and reprogramming the ICD could have an impact on mortality, not to mention possible complications associated with invasive interventions. The shock itself done during the test may have an impact on patients with established cardiac disease. Defibrillation has been shown to increase troponin level [62]. Any shock, even when inappropriate, has been associated with increased mortality [63].
- DFT does not predict future successful defibrillation in a reliable manner [18]. This may be related to the probabilistic nature of the test. It has also been shown that DFT change acutely and chronically [64-65]. This could result in the improvement of high DFT, but may also result in a patient with normal DFT developing high thresholds with time. It is estimated that about 29% of deaths in ICD recipients are still due to arrhythmias that could not be terminated by the ICD [66].
- Ventricular fibrillation induced in the hospital is not the same as the real world arrhythmia. Induced VF tends to be more organized than spontaneous VF [67]. In the clinical setting, many patients have ventricular tachycardia rather than VF or even do not have any arrhythmia at all during the lifetime of the implant [2,68-69]. For these patients DFT test may be misleading or may not have any relevance at all.

It is therefore important to have to prospective randomized study to give us a clear answer. One prospective, but not randomized study (SAFE-ICD) showed no benefit of DFT testing [60]. The result of an ongoing study (SIMPLE trial) may give a more clear direction once finished [70].

The approach to DFT testing has changed over time. A recent study in 111 Italian centers over the period 2007 to 2010 involving 2,082 patients documented the trend change [71]. It reported DFT testing to be performed in 38% of patients with the incidence declining annually from 36% in 2007 to 28% in 2010. In 13% of centers, the test was performed routinely, and in 38% it was not performed at all. The reasons for not performing DFT testing in this survey were the policy of the center in 44%, a primary indication for the implant in 31% and doing a device replacement in 15%. Not doing DFT testing can certainly make the ICD implant simpler. The simplification is not just related to the procedure itself, but starts with the initial step of taking the consent from the patient. It is not a simple task to explain the risk to the patient in a lay term without confusing him. A physician has to explain that after the surgery has finished successfully, there will be a need to stop the heart; and that there is a chance, even though very small, that he may have a problem like stroke or that we may not be able to restore his heart to beat back again.

Author	Year	N	Comment
Favor DFT testing			
Marchlinski et al [54]	1988	33	Patients with low DFT (n=19) had 100% success rate of clinical arrhythmia termination as compared to 73% (n=14) in the high threshold group
Pires et al [22]	2006	835	Long term survival was lower in the no DFT testing group (n=203) in comparison to DFT and safety margin testing (n=632)
Hall et al [55]	2007	112	Higher mortality seen in patients who did not have DFT testing because of contraindication (n=55) as compared to a random sample who had DFT testing performed (n=57)
Against DFT testing			
Epstein et al [26]	1992	1946	There was improved mortality among patients with high DFT who received ICD (n=71) versus those who did not receive ICD (n=16)
Russo et al [30]	2005	1139	No difference in mortality among patients with high DFT who had intervention (n=34) versus who did not have intervention (n=37)
Blatt et al [56]	2008	717	No difference in mortality between lower (< or =10 J) (n=547) versus higher (n=170) DFT groups
Bianchi et al [57]	2009	291	No difference in mortality between Italian centers that perform DFT testing routinely (n=137) versus centers that do not perform DFT testing (n=154)
Michowitz et al [58]	2011	256	No difference in mortality between CRT-D patient who had DFT testing (n=204) versus who did not have DFT testing (n=52)
Codner et al [59]	2012	213	No difference in mortality between DFT testing (n=80) and no DFT testing (n=133) groups
Brignole et al [60]	2012	2120	Prospective but non randomized evaluation of DFT testing (n=836) versus no DFT testing (n=1284) showed no difference in mortality

Table 5. Studies favoring and against DFT testing.

6. Conclusion

The approach to DFT testing has changed since ICD's were first introduced. It has changed from being an essential part performed in all the patients to being done in less than one third of the patients at current time. The need for DFT testing is a balance between benefit and risk with studies showing conflicting results. Most recent studies show equal benefit risk ratio for DFT testing. A prospective randomized study is needed to resolve the issue and there is currently one being performed. When this study is finished it should give a more clear answer regarding this issue.

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