Defibrillation Testing During ICD Implantation – Should we or Should We Not?

Justin Hayase¹, Noel G. Boyle¹

¹UCLA Cardiac Arrhythmia Center, UCLA Health System, David Geffen School of Medicine at UCLA, Los Angeles, CA, USA.

Abstract

The implantable cardioverter defibrillator (ICD) is an established therapy for improving mortality for primary and secondary prevention of sudden cardiac death. Whether to perform defibrillation threshold testing (DFT) either intraoperatively or post-operatively remains a controversial issue. The DFT is defined as the minimum energy required at which two shocks can successfully terminate ventricular fibrillation and dates from the era of surgically implanted devices with epicardial patches. Typically, a safety margin of at least 10J is employed for device programming, though some trial data suggest that a margin of 5J could be just as effective. Various methods have been utilized to perform DFT testing, and no particular method has been shown to be superior to another (Figure 1). Previously, guideline recommendations addressed the indications for ICD implantation but did not comment on DFT testing. Recent consensus statements now provide some guidance as to when it is appropriate to perform or not perform DFT testing in light of new trial data. This review will address some of the risk factors for having a higher DFT, impact of DFT testing on patient outcomes, and some of the risks and contraindications of DFT testing.

Introduction

The implantable cardioverter defibrillator (ICD) is an established therapy for improving mortality for primary and secondary prevention of sudden cardiac death. Whether to perform defibrillation threshold testing (DFT) either intraoperatively or post-operatively remains a controversial issue.¹-⁶ The DFT is defined as the minimum energy required at which two shocks can successfully terminate ventricular fibrillation and dates from the era of surgically implanted devices with epicardial patches.⁷ Typically, a safety margin of at least 10J is employed for device programming, though some trial data suggest that a margin of 5J could be just as effective.⁸ Various methods have been utilized to perform DFT testing, and no particular method has been shown to be superior to another [Figure 1]. Previously, guideline recommendations addressed the indications for ICD implantation but did not comment on DFT testing.⁹ Recent consensus statements now provide some guidance as to when it is appropriate to perform or not perform DFT testing in light of new trial data.¹⁰ This review will address some of the risk factors for having a higher DFT, impact of DFT testing on patient outcomes, and some of the risks and contraindications of DFT testing.

Risk factors for higher defibrillation threshold and troubleshooting high thresholds

Certain patients may be more likely to have a higher DFT, which comes primarily from observational study data. Higher risk patients include those with non-ischemic cardiomyopathy, younger patients, lower ejection fraction, longer QRS interval, undergoing generator change or replacement, or taking amiodarone.¹¹-¹² It should be noted, however, that no single variable is a strong clinical predictor of high DFT.¹ One history of ventricular arrhythmias does not seem to predict risk for high DFT based on current data.¹⁰ Various techniques can be employed in order to achieve an adequate safety margin. In the INTRINSIC RV study of 1530 ICD patients, there were 59 patients who did not initially meet the 10J safety margin. An adequate 10J safety margin was achieved in all patients by reversing polarity in 56% of patients or repositioning the RV lead in 32%. Adding a subcutaneous array or repeating testing at a later date were other strategies utilized in 2% of patients each.¹³ Repeating testing at a later date may allow for better optimization of heart failure medical therapy and performing device revision if needed. In a series published by Vischer, et al. there were nine patients who initially did not meet the 10J safety margin. An acceptable DFT was achieved by changing polarity, modifying the SVC coil to either “on” or “off”, revising the “pocket” or repositioning the generator, adding a subcutaneous array, changing to a higher energy device, or adding a coronary sinus coil.¹⁴ A series by Cesario, et al. also reported successful implantation of azygous vein coils in order to achieve adequate safety margins.¹⁵ In a study by Guenther, et al., of 783 patients who underwent ICD implantation, eleven patients had failure of DFT testing. In two patients, there was sensing failure requiring lead modification. In three patients, reversing polarity was sufficient to achieve acceptable thresholds. The remaining six required either subcutaneous array or lead revision. Additionally, in this study, there was no difference in DFT efficacy based on single versus dual coil or based on different manufacturers.³

Impact of DFT testing on patient outcomes

The impact of DFT testing on patient outcomes is still...
controversial. As devices and techniques improve, the yield of DFT testing (requiring intervention or inability to achieve <10J margin) has progressively decreased. Recent observational studies suggest the yield of DFT testing is approaching 3%.\(^3\) (Table 1)

Furthermore, the impact of DFT testing on outcomes has been unclear. In an observational cohort of 835 patients by Pires, et al., overall long-term survival was significantly better in the group that did not undergo DFT testing.\(^16\) In another cohort of 256 patients by Michowitz, et al., there was no difference in overall survival between patients who were tested and those who were not tested.\(^17\) Data from the SCD-HeFT trial suggests that any ICD shocks, whether appropriate or inappropriate, are associated with increased mortality.\(^18\) However, meta-analysis data suggests that while appropriate shocks portend poorer outcomes, inappropriate shocks are not associated with increased mortality.\(^19\) Whether DFT testing shocks themselves are associated with poorer outcomes is unknown.

Recently, two large clinical trials, the NORDIC and the SIMPLE trials, have attempted to address the question as to whether or not DFT testing affects patient outcomes.\(^20,21\) The NORDIC trial was a randomized, non-inferiority study of 1077 patients undergoing ICD implantation. All subjects had ICD shocks programmed to 40J regardless of DFT testing results and were followed for one year. The majority (65%) of patients had ischemic cardiomyopathy, and a minority (11%) were on Amiodarone. There was no difference in the primary end-point of first shock efficacy between the two groups. There was a significant difference in intraoperative hypotension, which occurred more frequently in the DFT testing group than in those without DFT testing. Notably, patients undergoing right-sided implants or sub-cutaneous ICDs were excluded from the trial.

The SIMPLE trial was another randomized, non-inferiority study of 2500 patients that compared DFT testing to no DFT testing, with all subjects having ICD shocks programmed to 31J. Subjects were followed for an average of one year. The primary outcome was a composite of failed appropriate shock or arrhythmic death. The no DFT testing group was found to be non-inferior to the DFT testing group with regards to the primary outcome. (Figure 2) Again, the majority of patients had established coronary artery disease (65%) and a minority was taking Amiodarone (15%). Also, subcutaneous devices and right-sided implants were excluded.

### Areas of uncertainty and special patient populations

These recent trial data show that standard ICD programming without DFT testing is non-inferior to DFT testing at the time of device implantation. However, data are still lacking regarding DFT testing outside of the time of initial implant. There is no data to support annual DFT testing in high risk patients, though historically, this was common practice. Some argue for repeat DFT testing with certain changes in clinical condition such as when changing antiarrhythmic therapy (e.g. – initiation of amiodarone) or if concerned about a lead status; however, current guidelines do not address this, and routine follow-up testing is of low yield.\(^10,22\) Additionally, whether to perform DFT testing at the time of generator change remains unclear, though in limited data, reported DFT failures seem to occur at rates similar to initial device implantation.\(^4,14\)

Congenital heart disease patients also pose particular challenges with regard to implantation of ICDs owing to variable anatomy. Data are minimal for this patient population. In a multicenter study of 443 congenital heart disease patients by Berul, et al., the reported rate of high or inadequate DFT was similar to that reported in the general patient population at 2%.\(^23\) However, this experience can be quite variable. A study by Stephenson, et al. described \(^24\) congenital heart disease patients who underwent ICD implantation who could not receive a transvenous coil or epicardial patch. Four patients had a high DFT, representing 16% of the studied population.\(^24\) Additionally, follow-up DFT testing in this patient group may be of higher yield, particularly as these patients grow and generally are more active than the elderly adult population.\(^25\)

### Risks and contraindications of DFT testing

Although rare, there are risks associated with DFT testing. Studies suggest that life-threatening complications occur at a rate of 0.17-0.4% and the mortality rate is 0.016-0.07%. Life-threatening complications generally result from the induction of ventricular fibrillation and include events such as stroke, pulmonary embolism, or prolonged resuscitation.\(^26,27\) Kolb, et al. performed a risk-benefit
analysis by using estimates of mortality reduction of 7-8% with an ICD and DFT testing yield of 2.5%. Under these assumptions, the mortality prevention rate by DFT testing is less than 0.2%, which would imply that the number needed to undergo DFT testing in order to save one life is 500. Depending on the estimated risk of life-threatening complications (0.17% versus 0.4%), DFT testing may provide either a favorable or unfavorable risk. While DFT testing does not come with additional cost, per se, since there appears to be equipoise in terms of risk and benefit based on current literature, DFT testing seems to be cost neutral.

Absolute contraindications to DFT testing include intracardiac thrombus, atrial fibrillation without anticoagulation, severe aortic stenosis, acute coronary syndrome and hemodynamic instability requiring inotropic support. Relative contraindications include severe unrevascularized coronary artery disease, recent coronary artery stent placement, recent stroke or transient ischemic attack, and hemodynamic instability not requiring inotropic support.

In the large trials that established the benefit of ICD implantation, DFT testing was performed routinely per research protocols. Currently, FDA approved labels for usage of ICDs include information on performing DFT testing at the time of device implantation, which is at the discretion of the implanting physician. However, as devices have improved, the yield of such testing has declined, and we now have randomized trial data on patient outcomes with regards to DFT testing. These data would suggest that there is no clinical benefit to performing routine DFT testing, and significant adverse events, though rare, can occur. Thus, it would seem prudent to perform DFT testing in only select individuals in whom there is a high expected yield, such as in those undergoing right-sided implants, subcutaneous device implantation, or in patients with multiple risk factors for a high DFT such as younger patients with non-ischemic cardiomyopathy on amiodarone, or in patients with complex anatomy such as those with congenital heart disease.

Conclusions

Figure 1: Various methods to determine DFT at time of ICD implant. “s” indicates defibrillation success. “f-resQ” indicates failure followed by rescue shock. “LED” indicates lowest energy tested that defibrillates. Adapted from Swerdlow, et al.

In the large trials that established the benefit of ICD implantation, DFT testing was performed routinely per research protocols. Currently, FDA approved labels for usage of ICDs include information on performing DFT testing at the time of device implantation, which is at the discretion of the implanting physician. However, as devices have improved, the yield of such testing has declined, and we now have randomized trial data on patient outcomes with regards to DFT testing. These data would suggest that there is no clinical benefit to performing routine DFT testing, and significant adverse events, though rare, can occur. Thus, it would seem prudent to perform DFT testing in only select individuals in whom there is a high expected yield, such as in those undergoing right-sided implants, subcutaneous device implantation, or in patients with multiple risk factors for a high DFT such as younger patients with non-ischemic cardiomyopathy on amiodarone, or in patients with complex anatomy such as those with congenital heart disease.

Conflict Of Interests
None.

Disclosures
None.

References


16. CBFordyce, ASHkell, YLKoklyheena, SMLindner, JPPiccin, RCBecker, SDBerkowitz, GBreithardt, KAFox, JLHalperin, GJHankey, KWMahaffy, CCNessel, DSEnger, MRPatel. On-treatment outcomes in patients with worsening renal function with rivaroxaban compared with warfarin. Insights from ROCKET AF. Circulation. 2015;0:0–0.


24. HXa, CTRuff, RPGiugliano, SAMurphy, FNordio, IPatet, MShi, MMercuri, EMAntman, EBraunwald. Concomitant use of single antiplatelet therapy with edoxaban or warfarin in patients with atrial fibrillation. Analysis from the ENGAGE AF-TIMI 48 trial. 2016;0:0–0.


