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Review / Derleme

Avoidance of defibrillation threshold testing at the time of internal defibrillator insertion: is it safe?

İnternal defibrilatör takılması sırasında defibrilasyon eşik testinden kaçınılması: Güvenli mi?

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This article consists of a subject review supported by a short-term pilot study which was conducted prospectively to shed light into the controversial question regarding the necessity of having the defibrillation threshold measured at the time of the implantable cardioverter defibrillator implantation. Answering this question will have an important impact on reducing the well-documented morbidity and mortality, making the operation simpler and cost-effective.

Key words: Cardiac arrhythmia; internal defibrillator; ventricular fibrillation.

Bu makale implantabl kardiyoverter defibrilatör takılması sırasında defibrilasyon eşiğinin ölçülmesi gerekliliğine ilişkin tartışmalı bir soruya ışık tutmak üzere, ileriye dönük olarak yürütülen kısa süreli önemli bir çalışma ile desteklenen bir konu incelemesinden oluşmuştur. Bu sorunun yanıtlanması, işlemi daha kolay ve maliyet etkin bir hale getirerek, iyi düzeyde belgelenmiş morbidite ve mortalitenin azaltılması üzerinde önemli bir etkisi olacaktır.

Anahtar sözcükler: Kardiyak aritmi; internal defibrilatör; ventriküler fibrilasyon.

Implantable cardioverter-defibrillators (ICDs) have consistently been shown to reduce the death rate among people at risk for ventricular arrhythmias (primary prevention)[1] and for survivors of cardiac arrest (secondary prevention).[2] The advanced pacing, cardioversion, and defibrillation capabilities of modern ICD devices have contributed to their safety, efficacy, and widespread use as mortality-reducing interventions.[1-3] Since the emergence of ICDs thirty years ago, defibrillation threshold (DFT) testing has been the standard of care during implantation, despite the absence of compelling evidence that testing improves outcomes.[4,5] The traditional approach to DFT testing involves the induction of ventricular fibrillation (VF) in order to assess: *(i)* reliable sensing *(ii)* consistent detection of VF, and *(iii)* adequate shock strength.[6,7] The DFT, defined as the lowest amount of energy that achieves defibrillation, is the most widely used index for defibrillation efficacy. To ensure an adequate safety margin, a 10JOLS (J) difference between the DFT and the ICD's maximum output has traditionally been required. Early studies have indicated that adequate safety margins protect against failed defibrillation and sudden cardiac death.[7]

In the past, DFT testing has guarded against low DFTs since early devices often required altering their shock polarity and the location, number, or type of electrodes.[7] However, advances in ICD technology and lead design have led studies to report excellent device performance without the need for threshold testing.[7-9] In addition, DFT testing is not without risk; studies have reported a risk of lethal and disabling complications attributable to the procedure.[4,10-12] Furthermore, a patient undergoing DFT testing will be burdened with the costs, risks, and complexity of general anesthesia and hemodynamic monitoring which are required for the procedure.

The aforementioned risks of the prophylactic procedure coupled with the increasing sophistication of ICD devices have sparked a debate in the literature regarding the necessity for DFT testing.[1,9,10,13]

There has been substantial controversy in recent literature concerning the risks versus the benefits of the DFT procedure.[6-8,14] In the early days of ICD development, the devices were prone to having overly high defibrillation thresholds, and DFT setting was an understood requirement to ensure reliable performance.[6]

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Studies estimated that approximately 15% of patients with monophasic shocks required system modification for new high-voltage coils or epicardial patches.[3] However, with the advent of modern ICDs, defibrillation efficacy has risen due to high maximum output to DFT ratios, rapid charge times, and biphasic waveforms.[6,15,16]

Despite the rapid pace of ICD technology development, the risks of the DFT procedure have only begun to be studied in the past decade. Alarmingly, several recent studies have shown that serious complications are associated with this prophylactic procedure.[4,11] One study examined DFT testing-related outcomes associated with a total of 19.067 ICD implants performed in Canada between 2000 and 2006. The study found three deaths, five strokes, and 27 episodes of prolonged resuscitation, all attributable to threshold testing.[4] This may underrepresent the true risk of the procedure since the sickest patients were not tested.[4] Ironically, the sickest patients are the ones most at risk for defibrillation failure. In one series of peri-implant DFT testing, 12 patients required on average five to 17 shocks to defibrillate, and troponin elevation indicative of myocardial damage was reported in five patients postoperatively.[10] Also, death due to cerebrovascular stroke one day after DFT testing was reported in two patients out of 440 in a study of ICD-related complications.[12]

The need for general anesthesia, even for a short period, is also not without risk. This occurs particularly in patients with poor ventricular function and those with underlying lung disease or sleep apnea.[7]

Given the potentially lethal complications of the procedure, no matter how rarely they occur, and studies supporting the efficacy of modern ICDs, one might wonder whether DFT testing may actually precipitate more harm than it prevents. Indeed, several recent studies have supported the conclusions reached by our study.[8,9,13,17] Namely, a cohort study of 835 consecutive ICD patients revealed that successful ventricular arrhythmia normalization by the ICD did not significantly differ between patients undergoing normal DFT testing, limited defibrillation safety margin testing, and no testing.[8] In addition, threshold testing was not found to relate to long-term clinical outcomes in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). Specifically, DFT testing data from 717 patients in the study suggests that threshold testing was irrelevant to successful ICD treatment of ventricular tachycardia (VT) and ventricular fibrillation (VF).[9] Similarly, a European multi-center study enrolling 291 patients reported no significant differences between DFT-tested and untested patients in all-cause, cardiovascular, and sudden cardiac death mortality.[17] Furthermore, a formal decision analysis found that routine defibrillation testing may confer little significant survival advantage, with nearly identical five-year survival rates associated with DFT testing versus no testing.[14]

A pilot study was performed at our center to add some more data to this review in an attempt to verify whether DFT testing should be a necessary part of routine ICD implantation.

Sixty consecutive patients who required internal defibrillator insertion were enrolled at the Maritime Heart Center, Halifax, Nova Scotia, Canada. Defibrillator lead models included Medtronic Passive Fixation (6944), Medtronic Active Fixation (6947), St. Jude Passive Fixation (7170), and St. Jude active fixation (7120). Indications for ICD implantation included: ischemia-related ventricular arrhythmia (n=39), low ejection fraction prophylactic measures (n=18), and familial cardiomyopathy (n=3).

All patients underwent fluoroscopy-guided, transvenous single-lead defibrillator insertions. The criteria of accepted lead position were: *(i)* The tip of the lead is at the apex of the right ventricle, *(ii)* R wave sensing >8 mm, and *(iii)* pacing threshold <0.6 mV.

Devices were implanted by full-time cardiovascular surgeons. All patients signed an informed consent form before undergoing the procedure. Devices were tested in all patients. During DFT testing, VF was induced, and an adequate safety margin was defined as 10J below the maximum output of the ICD pulse generator.[7] All patients underwent arterial hemodynamic monitoring and general anesthesia for the duration of the testing.

No cases revealed poor defibrillator pacing or poor defibrillator thresholds. Neither repositioning of the leads nor ICD system modification was necessary.

This study, in spite the small number of patients, found that in a consecutive population of patients undergoing ICD implantation, DFT testing was unnecessary to ensure proper pacing and defibrillation. In all patients, the leads were in a good position as determined by fluoroscopic imaging, and the ICD had adequate pacing thresholds.

If DFT testing truly has limited efficacy in improving patient outcome, eliminating the testing step will free scarce healthcare resources that could be applied elsewhere. Indeed, a US trial found that the elimination of pre-hospital discharge testing resulted in a savings of $1.800 United States dollar per patient after six months, with no difference between groups in terms of ICD complication rates or unanticipated

hospital admissions.[13] In a similar Canadian study, ICD insertion was found to be $844 Canadian dollars more expensive when DFT testing was performed versus no testing.[18]

In addition to reliable modern ICD performance, the predictive value of DFT testing has also been criticized on several theoretical grounds. For instance, it has been argued that the induction of VF more closely resembles electrocution rather than clinical VF, which typically occurs due to myocardial ischemia.[15,19] Furthermore, DFT testing is performed in deeply sedated patients, which is in contrast to spontaneous ventricular arrhythmias which are often triggered by electrolyte imbalances, worsening heart failure, high sympathetic tone, or ischemia.[5] Thus, reasonable doubt can be cast on the validity of induced VF as a model for clinical arrhythmias.

Additionally, some studies suggest a significant proportion of implanted ICDs will never treat spontaneous VF.[15,20] Many ICDs implanted for prophylactic purposes will predominantly treat ventricular tachycardia, which has a substantially lower cardioversion energy than the DFT required for VF.[21] One study suggests that 40% of ICDs implanted for primary prevention of sudden cardiac death will not detect any sustained ventricular arrhythmias during their six-year battery life.[15] As well, the probabilistic nature of defibrillation ensures that multiple successive shocks at less than the DFT have the potential to successfully terminate an episode of VF.[22,23] It follows that even an unlikely patient with a high DFT detected during testing will not necessarily succumb to an episode of VF. Therefore, DFT testing may not, in most cases, confer utility in improving patient outcome.

The specialized nature of the DFT testing procedure may restrict therapy in regions where electrophysiologists are scarce. Perhaps if the testing step was not performed, a greater range of physicians would be able to implant ICD, including those currently implanting pacemakers.[20]

From the above review, it can be concluded that the higher effectiveness of modern ICD devices coupled with the risks and costs associated with DFT testing clearly point to a revision in established practices. The elimination of DFT testing in current practice may be warranted if the lead is in a good position and has good pacing thresholds.

Finally, to support the above conclusion further, additional studies should aim to examine the relationship between DFT testing, mortality, and ICD performance as well as the long term prognosis.

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REFERENCES

1. Buxton AE, Lee KL, Fisher JD, Josephson ME, Prystowsky EN, Hafley G. A randomized study of the prevention of sudden death in patients with coronary artery disease. Multicenter Unsustained Tachycardia Trial Investigators. N Engl J Med 1999;341:1882-90.
2. Zipes DP, Camm AJ, Borggrefe M, Buxton AE, Chaitman B, Fromer M, et al. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death) developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. Europace 2006;8:746-837.
3. Zipes DP, Roberts D. Results of the international study of the implantable pacemaker cardioverter-defibrillator. A comparison of epicardial and endocardial lead systems. The Pacemaker-Cardioverter-Defibrillator Investigators. Circulation 1995;92:59-65.
4. Birnie D, Tung S, Simpson C, Crystal E, Exner D, Ayala Paredes FA, et al. Complications associated with defibrillation threshold testing: the Canadian experience. Heart Rhythm 2008;5:387-90.
5. Duray GZ, Hohnloser SH. Defibrillation testing: the need for a definitive trial. J Cardiovasc Electrophysiol 2010;21:183-5.
6. Swerdlow CD, Russo AM, Degroot PJ. The dilemma of ICD implant testing. Pacing Clin Electrophysiol 2007;30:675-700.
7. Russo AM, Sauer W, Gerstenfeld EP, Hsia HH, Lin D, Cooper JM, et al. Defibrillation threshold testing: is it really necessary at the time of implantable cardioverter-defibrillator insertion? Heart Rhythm 2005;2:456-61.
8. Pires LA, Johnson KM. Intraoperative testing of the implantable cardioverter-defibrillator: how much is enough? J Cardiovasc Electrophysiol 2006;17:140-5.
9. Blatt JA, Poole JE, Johnson GW, Callans DJ, Raitt MH, Reddy RK, et al. No benefit from defibrillation threshold testing in the SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial). J Am Coll Cardiol 2008;52:551-6.
10. Joglar JA, Kessler DJ, Welch PJ, Keffer JH, Jessen ME, Hamdan MH, et al. Effects of repeated electrical defibrillations on cardiac troponin I levels. Am J Cardiol 1999;83:270-2, A6.
11. Frame R, Brodman R, Furman S, Kim SG, Roth J, Ferrick K, et al. Clinical evaluation of the safety of repetitive intraoperative defibrillation threshold testing. Pacing Clin Electrophysiol 1992;15:870-7.

12. Alter P, Waldhans S, Plachta E, Moosdorf R, Grimm W. Complications of implantable cardioverter defibrillator therapy in 440 consecutive patients. Pacing Clin Electrophysiol 2005;28:926-32.
13. Lurie KG, Iskos D, Fetter J, Peterson CA, Collins JM, Shultz JJ, et al. Prehospital discharge defibrillation testing in ICD recipients: a prospective study based on cost analysis. Pacing Clin Electrophysiol 1999;22:192-6.
14. Gula LJ, Massel D, Krahn AD, Yee R, Skanes AC, Klein GJ. Is defibrillation testing still necessary? A decision analysis and Markov model. J Cardiovasc Electrophysiol 2008;19:400-5.
15. Viskin S, Rosso R. The top 10 reasons to avoid defibrillation threshold testing during ICD implantation. Heart Rhythm 2008;5:391-3.
16. Wyse DG, Kavanagh KM, Gillis AM, Mitchell LB, Duff HJ, Sheldon RS, et al. Comparison of biphasic and monophasic shocks for defibrillation using a nonthoracotomy system. Am J Cardiol 1993;71:197-202.
17. Bianchi S, Ricci RP, Biscione F, Sgreccia F, Di Belardino N, Rossi P, et al. Primary prevention implantation of cardioverter defibrillator without defibrillation threshold testing: 2-year follow-up. Pacing Clin Electrophysiol 2009;32:573-8.
18. Healey JS, Dorian P, Mitchell LB, Talajic M, Philippon F, Simpson C, et al. Canadian Registry of ICD Implant Testing procedures (CREDIT): current practice, risks, and costs of intraoperative defibrillation testing. J Cardiovasc Electrophysiol 2010;21:177-82.
19. Lever NA, Newall EG, Larsen PD. Differences in the characteristics of induced and spontaneous episodes of ventricular fibrillation. Europace 2007;9:1054-8.
20. Wathen MS, DeGroot PJ, Sweeney MO, Stark AJ, Otterness MF, Adkisson WO, et al. Prospective randomized multicenter trial of empirical antitachycardia pacing versus shocks for spontaneous rapid ventricular tachycardia in patients with implantable cardioverter-defibrillators: Pacing Fast Ventricular Tachycardia Reduces Shock Therapies (PainFREE Rx II) trial results. Circulation 2004;110:2591-6.
21. Strickberger SA, Klein GJ. Is defibrillation testing required for defibrillator implantation? J Am Coll Cardiol 2004;44:88-91.
22. Zipes DP, Jackman WM, Heger JJ, Chilson DA, Browne KF, Naccarelli GV, et al. Clinical transvenous cardioversion of recurrent life-threatening ventricular tachyarrhythmias: low energy synchronized cardioversion of ventricular tachycardia and termination of ventricular fibrillation in patients using a catheter electrode. Am Heart J 1982;103:789-94.
23. Strickberger SA, Daoud EG, Davidson T, Weiss R, Bogun F, Knight BP, et al. Probability of successful defibrillation at multiples of the defibrillation energy requirement in patients with an implantable defibrillator. Circulation 1997;96:1217-23.