DETECTION OF DEFIBRILLATION THRESHOLD USING THE UPPER LIMIT OF VULNERABILITY FOLLOWING DEFIBRILLATOR IMPLANTATION

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Summary

Although the correlation between upper limit of vulnerability (ULV) and defibrillation threshold (DFT) has been well described, there has been no uniform DFT testing protocol taking the advantage of ULV after defibrillator (ICD) implantation. This study was designed to test DFT with the least number of fibrillation inductions using the ULV and to describe the most practical set of ICD during DFT following implantation. A total of 13 patients undergoing a new ICD implantation had a DFT induced with scanned T wave shock. The hypothesis that VF could be defibrillated with 5 J higher than the highest T-wave shock needed to induce VF or with 10 J if the T wave shock needed to induce VF was less than 5 J, was tested. The common features of five patients who did not fulfill the hypothesis were that T wave shock needed to induce VF was either under 5 J (4 patients) or high (1 patient).

We propose the first T wave and rescue shock set at 10 J and 15 J, respectively. If any of the scanned T wave shocks could not induce VF, then the T wave and the first rescue shock should be set at 5 J and 10 J, respectively. If the induction of VF has been unsuccessful with T wave shock at 5 J, then a high DFT should be expected. ***(Arch Turk Soc Cardiol 2003;31:451-7)***

Key words: *Defibrillator, defibrillation threshold, upper limit of vulnerability*

Özet

Defibrilatör İmplantasyonu sonrası Hasarlanabilir üst Sınırı Kullanarak Defibrilasyon Eşiğinin Belirlenmesi

Hasarlanabilir üst sınır (HÜS) ile defibirlasyon eşiği (DFE) arasında iyi bir uyum olsa da, defibrilatör implantasyonu sonrası HÜS'ın avantajını kullanarak DFE'yi tesbit eden belirgin bir metod yoktur. Bu çalışma HÜS avantajını kullanarak en az fibrilasyon oluşturarak DFE'nin saptanmasını ve DFE saptanmasında en ideal defibrillator ayarlamasını saptamaktır.

Yeni ICD implantasyonuna giden 13 hasta T dalga şoku taraması ile oluşturulan DFE'si saptanmıştır. "Ventriküler

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fibrilasyon (VF) oluşturmak için gereken en yüksek T dalga şokundan 5 J fazla defibrilasyon şokunun veya VF oluşturacak T dalga şoku 5 J'den az ise 10 J defibrilasyon şokunun başarılı defibrilasyon sağlayacağı" hipotezi test edildi. Bu hipotezi sağlayamayan 5 hastanın ortak özellikleri VF oluşturmak için verilen T dalga şoklarının 5 J altında (n=4) veya çok üstünde (n=1) olmasıdır.

İlk T dalga ve kurtarma şoklarının sırası ile 10 ve 15 J olarak programlanmasını öneriyoruz. Eğer 10 J T dalga şokları VF oluşturamadıysa ilk T dalga ve kurtarma şoklarının sırası ile 5 ve 10 J olarak programlanmalıdır. 5 J T dalga şoku ile VF indüklenmemiş ise yüksek DFE akla gelmelidir. ***(Türk Kardiyol Dern Arş 2003;31:451-7)***

Anahtar Kelimeler: *Defibrilatör, defibrilasyon eşiği, hasarlanabilir üst sınır*

Since the first description of electrical termination of ventricular fibrillation (VF) by Kouwenhoven [1], technical developments lead to a low defibrillation threshold (DFT). This development allowed manufacturing defibrillators small enough to be implanted in the pectoral area. Long-term efficacy of implanted defibrillators depends on their ability to defibrillate successfully in a variety of clinical status. Adequate testing of the device at the time of implantation requires determination of minimal effective defibrillation, so that an effective safety margin can be programmed. One of the most common used DFT test at implant uses a stepdown method starting at 24 J and stepping down in 6-J decrements. The endpoint of testing is 2 successes on the first two shocks or 3 successes of the first 4 shocks at or below 24 J. Enhanced DFT protocols, defibrillation efficacy method and upper limit of vulnerability (ULV) method have been described, but there is not a standard method for the detection of DFT between physicians. Therefore, most physicians practically adopt an abbreviated procedure to define a 'safety' margin for the defibrillator.

Ascending part of the T wave represents the vulnerable period of the cardiac cycle. A weak stimulus, namely a weak electrical shock, delivered during this period will induce VF. During the repeated shocks with increased shock energy levels, no more VF will be inducible at some point. The lowest energy given during the vulnerable period of cardiac cycle and that does not induce VF is called "upper limit of vulnerability". Upper limit of vulnerability represents the lowest energy shock level that does not induce VF following successful induction with lower energy levels. Upper limit of vulnerability hypotheses link ULV to defibrillation. Although the correlation between ULV and defibrillation threshold has been well described and defibrillation threshold was found to be slightly above the ULV[2,3], there has been no uniform defibrillation threshold testing protocol taking the advantage of ULV. The study was designed to test the hypothesis that VF could be defibrillated with 5 J higher than the highest T-wave shock necessary to induce VF or with 10 J if the T wave shock necessary to induce VF was less than 5 J. In other words, we hypothesized that there could be a correlation between DFT and ULV within a margin of 5 J.

METHODS and PATIENTS

Patients undergoing a new ICD implantation for standard clinical indications of life-threatening ventricular tachyarrhythmias were enrolled in this prospective study. The study was approved by Ethics Committee. The patients signed informed consent form before the procedure.

The patients were considered ineligible if they had right ventricular dysplasia (n=1), hemodynamic instability that would prevent prolonged sedation needed during DFT (n=2), right sided implantation (n=1), multisided ICD implantation (n=1), no inducible VT/VF by T wave shock (n=1), and refused to participate in the study (n=3).

Left ventricular ejection fraction was determined by either echocardiogram or by left ventriculogram. All patients had undergone a baseline electrophysiological study with (five patients on amiodarone) or without antiarrhythmic drugs. Programmed ventricular stimulation was performed at two basic drive cycle lengths (600 or 500, and 400 ms), with up to three extrastimuli (minimum coupling interval of 180 ms) delivered at twice diastolic threshold with a pulse width of 2 ms from at least two different ventricular sites. Induction of sustained monomorphic ventricular tachycardias or ventricular fibrillation was considered a positive result.

ICD Implantation

The type of ICD and the implantation technique were left to the operator's discretion. All ICD devices were inserted under rhythm- and O2 saturation-monitor and disposable adhesive defibrillator pads were applied to the patients in the anteroposterior orientation and attached to the external defibrillator. According to the operator's discretion, left infraclavicular or deltopectoral incision; the left subclavian vein puncture (single or twice) and/or left cephalic vein dissection; were performed. The ICD pocket was either subcutaneous or intra/subpectoral in location. First, the right ventricular lead was placed in the apex and lead parameters were measured. A pacing threshold <1.2 V, an R wave >4 mV, and an impedance between 500–900 Ohm (for high impedance leads not more than 1500 Ohm) were accepted. An atrial lead was then screwed or placed to the right atrial appendix, anterior or lateral wall. The leads were secured to the pectoral muscle with permanent sutures and the leads were connected to the generator and inserted into the preformed pocket. The parameters were then checked again via the device itself.

Fibrillation Induction, Vulnerability Testing and Defibrillation Protocol

Monophasic T wave shock was delivered using the "T shock" programmable feature of ICD for the induction of VF. The coupling interval of T wave shock was determined by measuring the time between the pace spike or the beginning of the QRS and the peak of the T wave recorded on the rhythm strip during VVI pacing at 400 ms cycle length. The initial programmed T wave shock energy was set at 15 J for 9 cases and 10 J for the last 4 cases (marked with * in table-1). The first rescue shock was programmed 5 J more than T wave shock. Induced sustained polymorphic VT with a duration > 3 seconds and cycle length < 250 ms was treated as the successful induction of ventricular fibrillation. If ventricular fibrillation was not induced, subsequent T wave shocks was given 20 ms earlier (T-20) for induction. If ventricular fibrillation was not induced, then T wave shock was introduced 40 ms earlier (T-40). If none of three shocks (T, T-20, T-40) induced fibrillation, the strength of the next T wave shock was decreased by 5 J to 10 J. The first rescue shock was set accordingly (15 J). The second rescue shock was set at 20 J except Defender IV device (ELA Medical, Robinson, France) in which the second shock was committed to maximal energy and was not programmable. If T wave shocks with 10 J were not successful, T-wave shock at 5 J was delivered and the first rescue shock was set at 10 J and the second one was set either 15 or 20 J. If ventricular fibrillation could not be induced with 5 J then a T-wave shock of <2.5 J was delivered and the first rescue shock was at 10 J. Ventricular fibrillation induction algorithm is depicted in Figure-1. The defibrillation was considered successful if a single 10 J of defibrillation, 2 consecutive defibrillations with 15 J, or 3 consecutive defibrillations with 20 J were successful in defibrillation according to the 1S, 2S and 3S protocol[4]. A tolerance of ±2 J was accepted on both T wave or defibrillation shocks. The patients received midazolam for sedation before and flumazelil when necessary at the end of the procedure.

RESULTS

Characteristics of patients

A total of 13 patients were selected from 22 patients undergoing a new ICD implantation

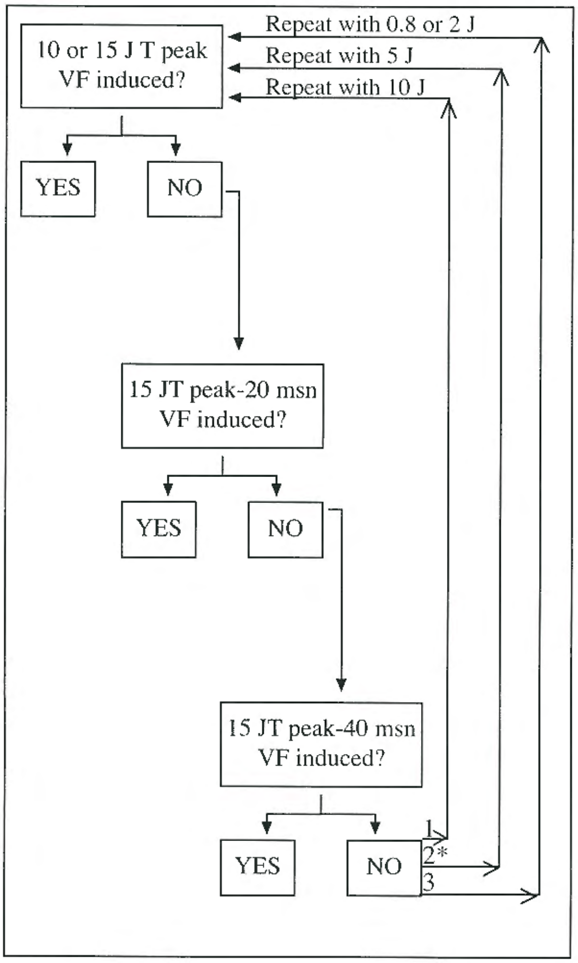

***Figure 1:** Algorithm of VF induction by T wave shock*

** İf the first T wave shock was started with 10 J, then the algorithm continues over 2*

between February-September 2001. The age range was 37-69 years with a mean of 54 ±9 years. Most of the patients were male (12 male, 1 female). The indications for ICDs in these patients were either survival from cardiac arrest due to VT/VF that was not associated with acute myocardial infarction (MI) (n=12) or syncope in one patient with previous MI and low ejection fraction who had inducible VT during programmed ventricular stimulation. Eleven patients have coronary heart disease (CHD). Dilated cardiomyopathy and idiopathic VF were diagnosed in the remaining 2 patients. All patients with CHD have a previous MI. The left ventricular EF was 35 ±10 % and programmed ventricular stimulation induced ventricular tachycardia/VF in all patients. The characteristics of the patients are summarized in table-2.

Nine patients received Photon Model V-230HV (St. Jude Medical, Sylmar, CA USA), 2 patients GEM II/III Models 7213 and 7273 (Medtronic Inc., Minneapolis, MN USA) and 2 patients Defender IV Model 612 (ELA Medical, Robinson, France). The R wave sensed was 12 ±6 mV and the ventricular capture threshold was 0.7 ±0.2 V at 0.5 ms. Procedural time required for DFT was 10 ±3 minutes and the amount of IV midazolam for deep sedation was 7 ±2 mg.

Correlation between upper limit vulnerability and defibrillation of ventricular fibrillation

The induction and defibrillation for each case was depicted in table-1. The first 8 cases satisfy the hypothesis that ventricular fibrillation can be defibrillated with 5 J higher than the highest T-wave shock needed to induce ventricular fibrillation. The last 5 cases in table-1 represent the patients in whom the energy required for successful defibrillation is more than 5 J higher than T wave shock which induces VF or more than 10 J in cases where the induction of VF necessitated T wave shock energy less than 5 J, i.e., these patients did not fulfill the criteria of hypotheses in that DFT and DFT were not within the 5 J of threshold.

In 13th case, the first T wave shock at 10 J induced VF but 15 J of 1st rescue shock was not effective in defibrillation. The second shock converted the patient into sinus rhythm with a maximal energy output since it was committed to maximal energy (31 J). The patient had Defender IV Model 612 and further T wave shocks at 15 J did not induced VF. This created a discrepancy between ULV and DFT. This patient needed to receive a total of 13 shocks to detect the DFT.

Table 1: The results of VF induction and defibrillation

NO	T Wave shock												number of VF induced/shocks given	DFT (J)	Fulfill the hypothesis?
	15 J			10 J			5 J			0.8/2 J					
	T	T-20	T-40	T	T-20	T-40	T	T-20	T-40	T	T-20	T-40			
1	-	-	-	-	-	-	+						1/8	10	Yes
2	-	-	+										3/7	20	Yes
3*				-	-	-	-	-	-	2J			1/11	10	Yes
4	-	-	-	-	-	-	-	+					1/9	10	Yes
5	-	-	-	-	-	-	-	-	+				1/10	10	Yes
6	-	-	-	-	+								2/8	15	Yes
7	-	-	-	+									2/6	15	Yes
8*				-	-	-	-	-	-	2J			1/7	10	Yes
9	-	-	-	-	-	-	-	-	-	-	-	0.8J	2/16	15	No
10	-	-	-	-	-	-	-	-	-	2J			4/10	16	No
11	-	-	-	-	-	-	-	-	-	-	-	0.8J	2/16	15	No
12*				-	-	-		-	-	-	2J		2/12	15	No
13*	-	-	-	+									4/13	22.5	No**

** The last 4 patients with an attempt of T wave shock starting at 10 J*

*** The first T wave shock at 10 J induced VF but 15 J of rescue shock was not effective in defibrillation. Further attempts of VF induction with T wave shock at 15 J were insuccessful*

DFT: Defibrillation threshold test

Table 2: Demographic and clinical characteristics of the patients

Male/Female	12/1
Age (year)	54 ±9
High/weight (cm/kg)	169 cm/80 kg ±6 cm/11 kg
Number of patients with previous MI	11
Number of diseased coronary artery	1.4 ±1
Previous MI	11
LV EF (%)*	35 ±10
Indicationl for ICD implantation (secondary/primary prevention)	12/1
R wave amplitude (mV)	12 ±6
V capture threshold (V)	0.7 ±0.2
Procedure time (min)	10 ±3
Midazolam (mg)	7 ±2
Defibrillation Threshold (J)	14 ±4
Coupling Interval of T wave shock (ms)	309 ±11

** LV EF: Left Ventricular Ejection fraction, MI: myocardiol infarction*

DISCUSSION

Measurement of the defibrillation threshold requires multiple inductions of ventricular fibrillation with 10-30 seconds of circulatory arrest. Potential complications including death have been reported(5,6,7) This prospective study was designed to establish DFT test with the least number of fibrillation inductions by using the advantage of high correlation between ULV and DFT in a practical approach. Induction of VF by simply 2 J of T wave shock will not help to estimate DFT, but unsuccessful T wave shock of 10 J during vulnerable period of repolarization strongly indicates a DFT equal to or less than 10 J based on upper limit of vulnerability hypothesis. The timing of the coupling interval of T wave shock is crucial and can affect the determination ULV. The most reliable way to measure the ULV is to scan the vulnerable period. Measuring at a single point in the T wave may find the critical degree of refractoriness in a region in which the electric field is not the weakest. Hwang et al, showed that increasing the number of scanning times in the T wave increased the average ULV by 4 J[8] Slight changes in the metabolic and autonomic state of the patient may alter the degree of refractoriness for a fixed point in the T wave. Therefore, the ULV dose-response curve obtained by scanning the T wave should have a smaller width than the one obtained by single T wave shock[9] . Chen et al[10] were not able to induce VF consistently at the mid-downslope supporting that T wave scanning should be preferred to induce VF with the closest ULV shock strength. In this study, the first coupling interval was set at the time between the pace spike or the beginning of the paced QRS complex and the T wave peak. If the shock is unsuccessful to induce ventricular fibrillation then the interval is decreased 20 and then 40 ms earlier. Defender IV Model 612 ICD did not provide elasticity in programming the coupling intervals since it can be programmed only predetermined values. For the purpose of the study, the closest value has been chosen in those devices for these cases. Additionally, this device has a committed set of the second rescue shock to maximal energy, thus eliminating the usage of the second defibrillation shock in determination of the defibrillation threshold and increasing the number of VF inductions needed.

The patients with a defibrillation threshold more than 5 J higher than the upper limit of vulnerability (5 patients marked with * in table-1) were not consistent with the hypothesis. The prominent common features of these patients were that T wave shock needed to induce VF was either under 5J (4 patients) or high (1 patient). There are possible explanations for this inconsistency. First, the pattern of T wave shock was monophasic although the defibrillation shock was biphasic, making the induction of VF harder. Secondly, the need of energy less than 5 J to induce ventricular fibrillation can be due to incomplete scanning of the T wave, resulting in underestimation of the ULV. Whether a shock will induce ventricular fibrillation or not is deterministic but exquisitely sensitive to differences in electrophysiological state at the time of the shock that are too small to detect or probabilistic and not determined until after the first postshock cycle. These may result in uncorrelated ULV and DFT.

Although this study does not test the potential myocardial damage caused by frequent T wave shocks, the total amount of energy given was 96 ±28 J per patient. A human study by Bessho R and Tanaka[5] has documented that the total amount of shock energy ranging from 51 to 378 J do not change the level of serum CPK-MB or the electrocardiogram.

Our study group had a somewhat higher average EF, but there are no indications that a lower EF increased the DFT or made the differences between ULV and DFT larger.

In his study, Swerdlow, CD has concluded that ICD implantations could be performed in >80% of implantable cardioverter-defibrillator recipients using a vulnerability safety margin based on a T-wave scan at 15 J without VF induction[12] In our study, in only one patient (No 13), 15 J of T wave shock did not induce VF but has high DFT (22.5 J). In other 4 patients (No 9-12), VF was not inducible with 15 or 10 J T wave scanned shocks, but still have acceptable DFT (maximum 16J) and the conclusions in the study by Swerdlow CD are applicable to these patients. But in the presence of one patient in 13 (no 13) with a high DFT in our study and the poor correlation between ULV and DFT when the T wave shock strength to induce VF is under 5 J, we believe that ULV can not be substituted for DFT but rather could be used in the reduction of VF inductions during DFT test.

Additionally, the time of the peak of the vulnerable zone has been stressed in a recent study by Swerdlow et al[13]. They proposed that the ULV method might be automated in an ICD by timing T-wave shocks using the electrogram derived from ICD itself.

Clinical Implication

Based on our findings, we propose an algorithm for detection of DFT using the ULV. The first T wave and rescue shock should be set at 10 J and 15 J, respectively. If any of the T wave shocks could not induce ventricular fibrillation, then the T wave and the first rescue shock should be set at 5 J and 10 J, respectively. If the induction of VF has been unsuccessful with T wave scanned shock at 5 J, then probability of high DFT should be expected (67%).

Long term reproducibility of this methodology needs to be evaluated with repeated DFT during follow-up.

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