Arch. Biol. Sci., Belgrade, 65 (2), 465-474, 2013 DOI:10.2298/ABS1302465K

DO WE NEED DEFIBRILLATION THRESHOLD TESTING? – A PILOT STUDY

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Abstract - Defibrillation threshold testing (DFT) is a standard procedure during implantable cardioverter defibrillator (ICD) implantation, however, it is not without risks. We compared the one-year follow-up period in ICD-implanted patients, with and without DFT performed during implantation, for preventive indication in regard to appropriate and inappropriate ICD detection and therapy. One group consisted of 20 patients without DFT; another was comprised of 20 patients where DFT had been performed. There was no difference in the development of ventricular tachyarrhythmias between the groups. Appropriate therapy of ICD was 100%. DFT is not a predictor for successful ICD detection and therapy of ventricular tachyarrhythmias.

Key words: Implantable cardioverter defibrillator, defibrillation threshold testing, sudden cardiac death, primary prevention; heart failure, treatment

INTRODUCTION

Defibrillation threshold testing (DFT) is performed by inducing ventricular fibrillation (VF) during implantable cardioverter defibrillator (ICD) implantation, to ensure reliable sensing, detection, and defibrillation, and it has been implemented for more than two decades (Liu et al., 2009). Today ICD technology, as well the algorithms for the diagnosis and treatment of ventricular tachyarrhythmias (ventricular tachycardia/ventricular fibrillation-VT/VF) have advanced, making ICD therapy more reliable (Calvi et al., 2010). Bearing in mind that DFT is not without some risks, such as embolic stroke in patients with atrial fibrillation, myocardial damage assessed through a troponin rise (Liu et al., 2009), transient depression of left systolic function and prolonged asystole (Kolb et al., 2006), (Frame et al., 1992), and DFT-related deaths, there is an on-growing demand in the scientific community to reassess the need for DFT during ICD implantation (Strickberger, 2004), (Neuzner, 2005).

The aim of this study was to compare the one-year follow-up period in ICD implanted patients (i.e. one group without DFT during implantation and one group with) for preventive indication related to appropriate and inappropriate ICD detection and therapy.

MATERIALS AND METHODS

Patient selection

Our study was a single-center, randomized trial. Patients undergoing ICD implantation for primary prevention according to the official guidelines of ACC/AHA/ESC/EHRA, 2008 (Zipes et al., 2006), (Epstein et al., 2008), (Wilkoff et al., 2008), (Dickstein et al., 2010) between December 2006 and June 2010 were included in our study. Data analysis was performed after the last 12-month follow-up in June 2011. The investigation conformed to the principles outlined in the Declaration of Helsinki (Br Med J 1964; ii: 177). All patients provided written informed consent, as approved by the Institutional Review Board, for data collection, management, and analysis. They were divided randomly 1:1 into two groups. These were as follows: a group comprised of patients that did not have DFT and which will be referred to as the "no-DFT-group", and a group of patients who had DFT and that was referred to as the "DFT-group".

ICD implantation and Defibrillation Threshold Testing

All ICDs were implanted at the Clinical Center of Serbia. A ventricular lead was introduced through the left cephalic vein or left subclavian vein, which was used as an alternative site of lead implantation. The standard protocol for VT/VF treatment in implanted ICDs allows the detected ventricular tachycardia (heart rate less than 180 beats/min) to be treated with the least aggressive therapy – antitachycardia "burst'" therapy (ATP). If a series of repeated ATP does not terminate ongoing tachycardia, low power (0.1-5J) synchronous cardioversion (CD) is the next therapy of choice by algorithm, and if this is futile, ICD delivers a defibrillating (DC) shock of maximal power (29-36J) (Milašinović, 2007). If the ventricular tachyarrhythmia is with a heart rate greater than 188 beats/min, ICD instantly delivers a DC shock. Also, these ICDs have antibradycardia pacing. In some patients, this is indicated at the implantation due to the nature of their disease, while in others this is a so-called "reserve therapy", because antibradycardia pacing is usually necessary after DC, when short cardiac arrest is registered.

Defibrillation threshold testing was performed during a short-term intravenous anesthesia using propofol or hypnomidate, by a method of 10 J voltage difference between a device's maximal DC shock and the obtained successful defibrillation voltage. The follow-up of ICD patients was performed at 1, 3, 6 and 12 months post implantation at our outpatient clinic. These visits included device interrogation and analysis of the printouts for appropriate and inappropriate therapy (shock delivery) in all implanted patients, as well as a check-up of the ICD device battery status.

Statistical analysis

The normality assumption for continuous variables was evaluated by the Kolmogorov-Smirnov test. Continuous variables are presented as means and standard deviations for normally distributed variables or as a median and interquartile range for non-distributed ones. They were compared using Student's unpaired t test or the Mann-Whitney rank sum test, as appropriate. Categorical variables are presented as counts and percentages and were compared with the chi-square when appropriate (expected frequency >5). Otherwise, Fisher's exact test was used. For all analyses, a two-sided $p<0.05$ was considered statistically significant.

The probability of the outcome of events was calculated using the Kaplan Meier method, and differences between these curves were analyzed by the long-rank test. The interactions of each of the factors (observed in this study, including DFT), and their effect on the probability of rhythm disturbance occurrence were analysed using the Cox proportional hazards model. All data were processed with the statistical package for social sciences, version 17 (SPSS, Chicago, Ill).

RESULTS

Forty patients underwent ICD treatment for pri-

Table 1. Patients' baseline characteristics.

	Total (n=40)	DFT not performed (n=20)	DFT performed (n=20)	P
Male, n (%)	33 (82)	16 (80)	17 (85)	1.00
Age, years (SD)	58 (14.0)	56 (13.3)	59 (14.9)	0.499
Diabetes, n (%)	9 (23)	3 (16)	6 (30)	0.451
Hypertension, n (%)	24 (60)	12 (60)	12 (60)	0.744
Dyslipidemia, n (%)	25 (62.5)	12 (60)	13 (65)	1.00
ICMP, n (%)	28 (70)	13 (65)	15 (75)	0.490
Non-ischemic CMP, n (%)	12 (30)	7 (35)	5 (25)	0.731
Previous MI, n (%)	24 (60)	9 (45)	15 (75)	0.053
LBBB/RBBB, n (%)	8 (20)	5 (25)	3 (15)	0.695
Digoxin, n (%)	7 (17.5)	5 (25)	2 (10)	0.407
Amiodarone, n (%)	28 (70)	14 (70)	14 (70)	1.00
ß blockers, n (%)	38 (95)	18 (90)	20 (100)	0.487
ACE inh, n (%)	34 (85)	16 (80)	18 (90)	0.661
Statins, n (%)	29 (72.5)	14 (70)	15 (75)	0.99
ICD Type, n (%)				
VR	34 (85)	16 (80)	18 (90)	0.661
DR	6 (15)	4 (20)	2 (10)	
Ejection fraction, % (IQR)	27.0 (12)	30.0 (16.0)	26.0 (4)	0.181
NYHA, n (%)				
I	31(77,5)	16 (80,0)	15 (75,0)	0.59
II	6 (15)	2 (10)	4 (20)	
III	3 (7,5)	2 (10)	1 (5)	

ICMP- Ischemic Cardiomyopathy; IM- Myocardial Infarction; LBBB- Left Bundle Branch Block; RBBB- Right Bundle Branch Block; IQR- interquartile range; NYHA- New York Heart Association

mary prevention of sudden cardiac death and were included in our study. The mean age of the tested population was 58±14 years, and predominantly male (82%). The no-DFT-group consisted of 20 patients of whom 80% were males, the mean age of the patients was 56±13.3 years, while 20 patients in the DFT-group were 59±14.9 years of age; 85% were male. There were no statistical significant differences in the frequencies of the evaluated demographic parameters (Table 1).

Our results showed no statistically significant difference in the development of VT/VF between the two groups registered at all follow-up visits performed 1, 3, 6, and 12 months after ICD implantation. At 1-month and 3-months of follow-up, in the DFT-group VT/VF occurred in 1 (5%) patient vs. 2 (10%) patients in the no-DFT-group (p=0.99). At the 6-month follow–up, VT/VF did not occur in any of the patients in the no-DFT-group, while it occurred in 2 (10%) patients in the DFT-group (p=0.487). VT/VF occurred in 4 (20%) patients in the no-DFT-group vs. 1 (5%) patient in the DFT-group (p=0.342) at 12-months of follow-up. If we divide ventricular tachyarrhythmias on VT and VF, the results show that at 1-months follow–up, in the DFT-group VT occurred in 1 (5%) patient, while in the no-DFT-group VT occurred in 2 (10%) patients. There was no VF noted in any of the patients (p=0.548). At 3-months follow-up, in the no-DFT-group VF developed in 1 (5%) patient; VT also developed in 1 (5%) patient. In the DFT-group there was no registered

Table 2. VT/VF occurrence at 1, 3, 6, and 12-month follow-ups.

	Total (n=40)	DFT not performed (n=20)	DFT performed (n=20)	p
VT/VF 1.month follow up, n (%)	3 (7.5)	**2 (10)**	**1 (5)**	**0.99**
VT1.month follow up, n (%)	3 (7.5)	2 (10)	1 (5)	0.548
VF 1.month follow up, n (%)	0 (0)	0 (0)	0 (0)	
VT/VF 3.month follow up, n (%)	**3 (7.5)**	**2 (10)**	**1 (5)**	**0.99**
VT 3.month follow up, n (%)	2 (5)	1 (5)	1 (5)	0.598
VF 3.month follow up, n (%)	1 (2.5)	1 (5)	0 (0)	
VT/VF 6.month follow up, n (%)	**2 (5)**	**0 (0)**	**2 (10)**	**0.487**
VT 6.month follow up, n (%)	2 (5)	0 (0)	2 (10)	0.487
VF 6.month follow up, n (%)	0 (0)	0 (0)	0 (0)	
VT/VF 12.month follow up, n (%)	**5 (12.5)**	**4 (20)**	**1 (5)**	**0.342**
VT 12.month follow up, n (%)	1 (2.5)	0 (0)	1 (5)	0.072
VF 12.month follow up, n (%)	4 (10)	4 (20)	0 (0)	

VT- ventricular tachycardia; VF- ventricular fibrillation

Table 3. NSVT occurrence at 1, 3, 6, and 12-month follow-ups

	Total (n=40)	DFT not performed (n=20)	DFT performed (n=20)	p
NSVT 1.month follow up, n (%)	7 (17.5)	2 (10)	5 (25)	0.407
NSVT 3.month follow up, n (%)	9 (22.5)	4 (20)	5 (25)	0.99
NSVT 6.month follow up, n (%)	12 (30)	6 (30)	6 (30)	0.99
NSVT 12.month follow up, n (%)	14 (35)	10 (50)	4 (20)	0.097

NSVT – non-sustained ventricular fibrillation

Table 4. AF occurrence at 1, 3, 6, and 12-month follow-ups

	Total (n=40)	**DFT not performed (n=20)**	**DFT performed (n=20)**	**p**
AF 1.month follow up, n (%)	9 (22.5)	3 (15)	6 (30)	0.451
AF 3.month follow up, n (%)	8 (20)	2 (10)	6 (30)	0.235
AF 6.month follow up, n (%)	9 (22.5)	3 (15)	6 (30)	0.451
AF 12.month follow up, n (%)	8 (20)	2 (10)	6 (30)	0.235

AF – atrial fibrillation

VF, while VT developed in 1 (5%) patient (p= 0.598). At 6-months follow-up VF did not develop in any of the patients, while VT developed in 2 (10%) patients in the DFT-group (p=0.487). At 12-months follow-up VF developed in 4 (20%) patients in the no-DFT-group, while in the DFT-group VF was not registered. In the DFT-group, VT developed in 1 (5%) patient, while in the no-DFT-group VT was not registered (p=0.072). All VT episodes in both groups were successfully terminated with burst therapy (ATP), while all VF episodes were terminated with a single DC shock, showing that therapy effectiveness was 100%. Throughout the period of follow-up in our population, VT/VF developed 13 times (VT developed 8

Table 5. Probability without rhythm disturbance by Kaplan Maier method

Rhythm disturbance		TIME				p
		1.month follow up	3.month follow up	6.month follow up	12.month follow up	
NSVT	DFT Performed	75%	60%	60%	60%	0.632
	DFT Not Performed	90%	80%	70%	45%	
AF	DFT Performed	70%	70%	70%	70%	0.462
	DFT Not Performed	85%	85%	80%	80%	
VT	DFT Performed	90%	90%	85%	85%	0.991
	DFT Not Performed	90%	85%	85%	85%	
VF	DFT Performed	100%	100%	100%	100%	0.037
	DFT Not Performed	95%	95%	95%	80%	
All Events	DFT Performed	60%	45%	40%	40%	0.893
	DFT Not Performed	75%	60%	55%	35%	

NSVT- non-sustained VT; AF – atrial fibrillation; VT – ventricular tachycardia; VF-ventricular fibrillation

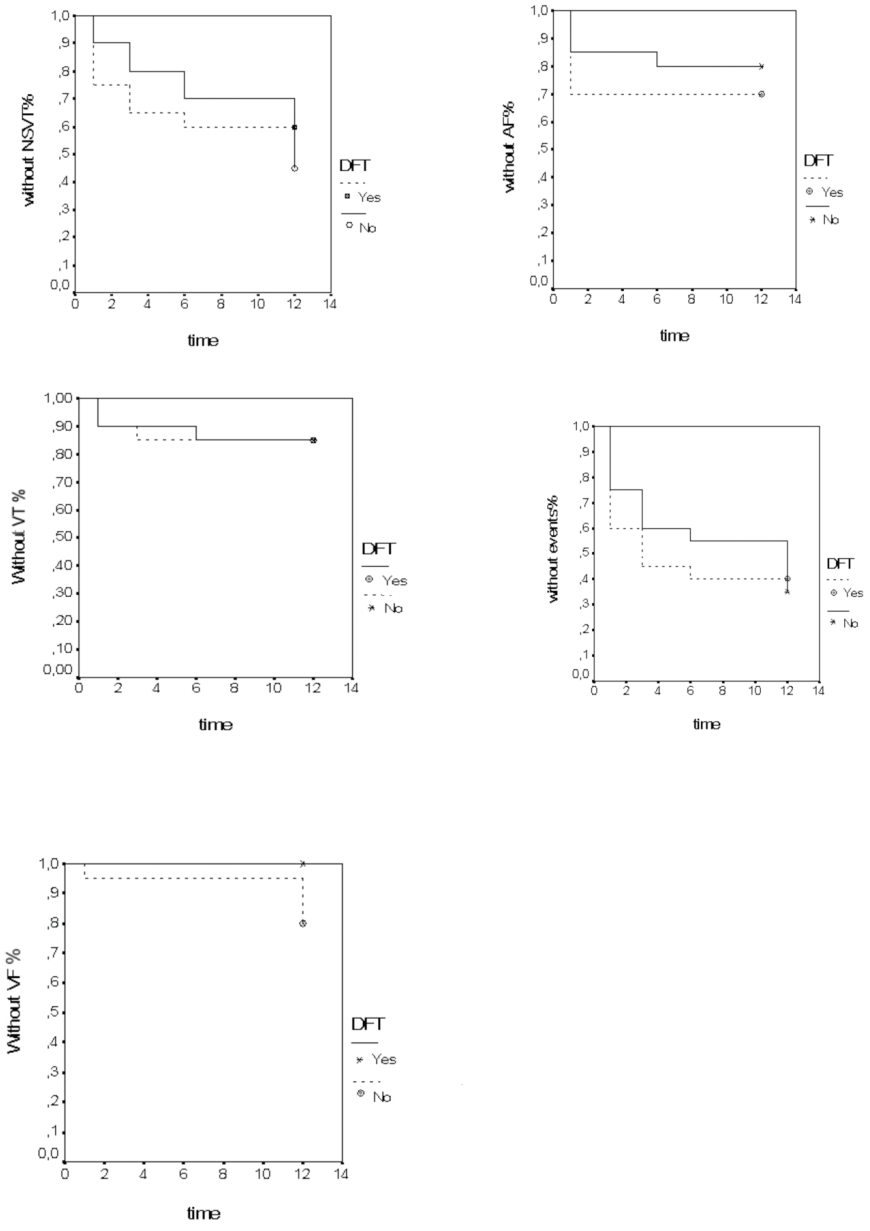
times, VF 5 times). In addition, the development of non-sustained ventricular tachycardia (NSVT) and atrial fibrillation (AF) did not statistically differ between the no-DFT-group and the DFT-group at 1, 3, 6, and 12-months of follow-up. Appropriate therapy (ATP or DC shock) deliverance of ICD was 100%. Over a one-year period, 9 (22.5%) patients developed VT/VF, while 31 (77.5%) patients did not develop VT/VF at all (p=0.001) (Tables 2, 3, 4).

The Kaplan Meier analysis showed a statistically significant difference between the DFT- and no-DFT-groups in probability, without rhythm disturbance occurrence for VF development (VF did not occur at all during the 12-month follow-up in the DFT performed group) (p=0.037). All VF episodes that occurred in the no-DFT-group were successfully terminated with a single DC shock. Kaplan Meier analysis did not show a statistically significant difference between groups with respect to the probability without rhythm disturbance occurrence for VT, NSVT and AF, which indicates good randomization (Table 5, Fig. 1).

Cox Regression analysis pointed out prior ischemia as a predictor of difference in probability for developing NSVT, while for all events (regardless of the type of rhythm disturbance) the predictor of difference was digoxin therapy, meaning that patients that were not on digoxin did not develop any of the rhythm disturbances within the 12-month period of observation. In addition, Cox regression analysis showed digoxin therapy as a predictor of difference in probability for developing VF. The Cox regression model did not establish DFT as a predictor of event occurrence.

DISCUSSION

In our study, during a one-year follow-up we did not detect any statistically significant differences in the development of VT/VF, NSVT and AF between the no-DFT- and DFT-groups. Thirteen episodes of VT/VF (8 episodes of VT, and 5 episodes of VF) were detected in 22.5% of our study population in the course of one year. Adequate therapy was delivered at all times of VT/VF development, while ICD did not de-



Figs. 1. Kaplan Maier curves of event occurence

liver any kind of therapy (neither ATP nor DC shock) in cases when NSVT or AF were the cause of rhythm disturbances, showing that appropriate shock occurrence was 100% in both groups. This speaks in favor of the hypothesis that DFT does not predict shock appropriateness, hence the better performance and efficacy of ICD. All VT episodes were terminated with ATP, and VF arrhythmias in both groups were terminated with a single DC shock, showing that appropriate therapy effectiveness was 100%. In the literature, the percentage of inappropriate shocks is 32% (Brady et al., 2005).

Present arguments in favor of DFT are obscure and questionable (Bianchi et al., 2011). The scientific community is divided between those in favor of DFT and those against it. According to Bianchi et al., in medical centers across Italy about 66% of device implantation has been done without DFT (Bianchi et al., 2011). According to the authors, the two main reasons for not performing DFT are center practice and primary prevention (Bianchi et al., 2011). This study showed that Italian doctors are concerned for the safety of patients undergoing ICD implantation for primary prevention with left ventricular dysfunction because of the potential deleterious effect of DFT due to their increased susceptibility to adverse events caused by VF induction (Bianchi et al., 2011). According to the European Heart Rhythm Association Survey, 19.3% of the 57 centers that responded to the Survey do not perform DFT during implantation procedures (Morgan, 2011). In the past we have noticed during follow-up visits that in patients in whom DFT was not performed due to their bad clinical condition during ICD implantation for primary prevention, the detection and therapy of ventricular tachyarrhythmias was adequate. This has led us to question our practice of DFT during ICD implantation.

Some of the reasons against DFT are the following: literature data suggest that induced VF is different from spontaneous VF. The latter is faster and more irregular than the former (Lever et al., 2007). This fact is important because the probability of defibrillation correlates with VF regularity (Makikallio et al., 2002). The characteristics of induced VF at ICD implantation are more similar to the process that occurs during electrocution and *commotio cordis*, while spontaneous primary VF is mostly caused by myocardial ischemia (Viskin, 2008). Features of induced VF, such as cycle length and vector-index, differ from one mode of induction to another; these features also reflect VF organization, which affects probability of defibrillation; hence the mode of VF induction has an impact on DFT (Viskin, 2008). Ventricular fibrillation regularity also correlates with the probability for defibrillation. There is a study suggesting that spontaneous VF is faster and with a lower degree of regularity than induced VF in the same patients (Viskin, 2008). Some studies on animals also suggest that the energy level required to terminate VF is not the same for induced VF and spontaneous ischemic VF that we are trying to treat, the latter being higher (Viskin, 2008), (Qin et al., 2002), (Walcott et al., 2002). The fact that physicians test the performance of ICDs at the implantation by inducing VF with the assumption that this arrhythmia mimics clinical arrhythmia, questions the medical significance and relevance of the whole process, when the clinical event we are inducing is completely pathophysiologically and morphologically different from the one we are trying to treat.

Viskin and Rosso pointed out in their article that the majority of implanted ICDs will never treat spontaneous VF (Viskin, 2008). The same article suggests that 40% of implanted ICDs would detect and treat VT/VF during one battery lifetime. Our results show that 22.5% of the implanted ICDs in our study population detected and treated VT/VF. ICD devices use lithium-vanadium batteries, which are a more reliable source of energy and have a predictable exploitation time. One battery lifetime is approximately 6 years long, but can vary depending on the frequency of DC shock delivery. In our study, a battery status check of all ICD devices was performed at each follow up visit. Since the need for DC shock therapy was not high in our study groups, none of the ICD devices needed battery change during the one-year follow-up period. The battery life expectancy of all implanted ICD devices in the present cohort of patients was over five years, so it was not realistic to expect any significant impact on battery life during the one-year follow-up period in both groups of patients. Also those patients that develop ventricular tachyarrhythmias are more likely to develop VT rather than VF; with ICD algorithm programming these VT episodes could be safely terminated with ATP without the need for DC shock (Viskin, 2008). Of the 13 episodes of ventricular tachyarrhythmias that occurred in our study groups during the one-year follow-up, 8 were VT episodes that successfully responded to antitachycardia pacing and did not require DC shock for termination.

In our study, we had no deaths reported within the 12 months of follow-up. Literature data concerning long-term mortality are equivocal. In the article by Pires et al, the results indicated that overall mortality was higher in the DFT no testing group. This result was overturned by the authors themselves with the fact that "sicker" patients (lower left ventricular ejection fraction, ischemic/non-ischemic cardiac myopathy, higher New York Heart Association-NYHA class) were included in the no-DFT-group, suggesting that the higher overall mortality may be influenced by other factors and not primarily by a lack of DFT, hence device therapy failure (Pires, 2006). The main cause of death in patients with NYHA class IV is progression of heart failure (Abraham, 2007). Our patients were without statistical significance for these comorbidities. While in our study prior ischemia was determined by Cox regression analysis as a predictor of difference in probability for developing NSVT, and digoxin therapy for the development of any of the rhythm disturbances, the Cox regression model did not establish DFT as a predictor of event occurrence (possible cause of inhomogeneity between the DFT- and no-DFT-groups in the severity of the disease) that could cause a possible pro-DFT bias.

The process of DFT carries its consequences that reflect the induction of VF and subsequent shock. It can cause myocardial damage, cardiac arrest caused by refractory VF, electromechanical dissociation, transient ischemic events, and patients with atrial fibrillation may develop embolic stroke. Unfortunately, sometimes it may even result in death (Calvi et al., 2010). In the article "the Canadian experience" by Birnie et al., 35 of 19,067 patients (0.18%) had a complication related to DFT. There were 3 deaths reported, 2 of which were due to electromechanical dissociation caused by VF induction, and 1 that was due to embolic stroke. Five (0.026%) patients suffered a cerebrovascular accident or transitory ischemic attack within 24 hours of DFT. Prolonged resuscitation was required in 27 (0.14%) patients (Birnie et al., 2008). We had no complications reported in either group of patients. Having all the above-mentioned in mind, it is understandable why many physicians have decided to abandon DFT. The number of ventricular tachyarrhythmic events in patients undergoing ICD implantation for primary prevention is usually smaller than the number of events in patients undergoing ICD implantation for secondary prevention (Capoferri et al., 2008), so a larger number of patients is needed. Our results are preliminary and we will continue to evaluate this type of patients in increasing numbers which will increase the statistical significance of our results.

Study limitations

There were several limitations to our study that need to be addressed. The first regards the number of patients, while the second regards the length of the follow-up periods. During the period of this study, this was the number of patients that were treated at our Clinic for primary prevention. Therefore, we could not have a greater number of patients; nevertheless, we wanted to share our experience with others. An increase in the number of individuals would probably influence the statistical significance of the obtained results, as would a longer follow-up period.

CONCLUSION

The results of this pilot study indicate that DFT may not be a predictor for successful ICD detection and therapy of ventricular tachyarrhythmias, and that the standard practice of DFT during ICD implantation in primary prevention could be re-evaluated. However, because of the small number of patients and a follow-up period of 12 months, it is not possible to draw a definite conclusion. This study is just a small contribution to the an ongoing debate on whether to perform DFT or not, and there is a need for a randomized prospective trial with a larger number of patients and a longer follow up period.

Acknowledgments - A part of this work was accepted for poster presentation at the 61st International Congress of the European Society of Cardiovascular and Endovascular Surgery (ESCVS) held in Dubrovnik, Croatia in April 2012, and was published as an abstract in the Journal of Cardiovascular Surgery 2012; 53(1-2):p 27. All authors have read and approved the manuscript.

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