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ORIGINAL ARTICLE

Shock or no shock – a question of philosophy or should intraoperative implantable cardioverter defibrillator testing be recommended?

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Abstract

OBJECTIVES: Implantation of implantable cardioverter defibrillators (ICDs) in patients with a high risk for life-threatening ventricular arrhythmias is a standard therapy. The development of new ICD leads, shock algorithms, high-energy defibrillators and rapid energy supply has improved the devices. Nevertheless, the discussion regarding 'shock or no shock' to test the system intraoperatively has not silenced yet.

METHODS: In this study, all 718 patients (60.0 ± 14.2 years old, 570 male) who were treated with a first ICD at our institution since 2005 were analysed. The indication for implantation was primarily prophylactic in 511 patients (71.3%). Underlying diseases included ischaemic cardiomyopathy (358 patients, 50%), dilated cardiomyopathy (270 patients, 37.7%) and others (12.3%). Mean ejection fraction was 27.4 ± 11.8%. Intraoperative ventricular fibrillation was induced with a T-wave shock or burst stimulation. The primary end-point was failing the initial intraoperative testing.

RESULTS: During the initial testing, 28 patients (3.9%) had a defibrillation threshold (DFT) >21 J. The mean age of these patients was 51 ± 14 years, ranging from 22 to 71 years, 20 were male, and the ejection fraction was 23.8 ± 11.8%. The indication for ICD implantation was prophylactic in 13 patients. Twenty-one of the 28 patients suffered from dilated cardiomyopathy, whereas seven patients had ischaemic cardiomyopathy. Twenty-four ICDs were implanted on the left side and four on the right side. None of the patients had been treated with amiodarone at the time of implantation. All patients achieved a sufficient DFT ≤21 J by changing the ICD leads, device repositioning and/or optimizing the shock configuration.

CONCLUSIONS: The standard of care intraoperative ICD testing remains necessary.

Keywords: Implantable cardioverter defibrillator • Intraoperative test

INTRODUCTION

Since introduction of implantable cardioverter defibrillators (ICDs) in the early 1980s by Mirowski *et al*. [1], multiple studies have extended the indication for placement of ICDs in patients with a high risk for life-threatening ventricular arrhythmias, as has been summarized in the guidelines for the treatment of acute and chronic heart failure [2]. Meanwhile, the implantation is a standard therapeutic method, which has been considerably improved over time by the development of new ICD leads, shock algorithms, high-energy defibrillators and rapid energy supply. The latest development in ICD capacitors was introduced 2005.

Yet, the discussion regarding 'to shock or not to shock' in order to test the system intraoperatively remains controversial. Supporting arguments for testing of the implanted system vary from quality control regarding lead reliability, appropriate detection of ventricular tachycardia and/or ventricular fibrillation (VF) and sufficient device functioning up to patient's safety [3, 4]. There are also multiple arguments against intraoperative testing, ranging from the avoidance of adverse events during the procedure to the clinical outcome through statistical analysis [5, 6]. Hence, review of the current literature does not answer the question of whether it can be recommended to refrain from testing a newly implanted ICD.

PATIENTS AND METHODS

Since 1996, our institution has implanted 1512 ICDs. To avoid bias of the study, all patients requiring ICD therapy participated. Within the study period from July 2005 until June 2011, 718 patients received their first ICD (one-, two or three-chamber ICD).

Exclusion criteria

Two patients had to be excluded from the study due to left ventricular thrombi. Of the remaining 716 patients, the primary endpoint of the study was patients failing the initial intraoperative testing of the system implanted.

Surgery

All patients underwent general anaesthesia for the operative procedure, which was performed by a cardiac surgeon. Leads were placed via a cephalic vein and/or subclavian vein. Only dual-coil defibrillation leads were implanted. Left ventricular leads were positioned either endocardially or epicardially (two patients received epicardial defibrillator patches owing to occlusion of both of their subclavian and jugular veins). All devices were implanted subpectorally.

The devices were implanted on the left side in 680 (96%) of the patients; only for exceptional reasons was the implantation performed on the right side (e.g. occluded left subclavian vein or pacemaker on the right side).

All implanted systems were high-energy ICDs with maximal deliverable shock energy ≥31 J (Biotronic, Boston Scientific, Medtronic and St Jude Medical). An adequate ventricular sensing of >6 mV and a pacing threshold of <1 V was attempted in all cases.

Testing

According to the protocol, VF was induced by T-wave shock or, if the T-wave shock failed to induce VF, by 50 Hz pacing. The test shock was programmed at 21 J. In the event of ongoing VF, external defibrillation was then used to terminate VF. If successful termination of VF could not be achieved with internal electrodes, the defibrillation lead was repositioned and testing repeated. Programming reversed polarity, use of a single coil and repositioning of the device caudo-medially or laterally were carried out as further options if the system still failed to terminate VF, with each step being tested again to reach a defibrillation threshold (DFT) ≤21 J.

Statistical analysis

Statistical analysis was performed with Stata 10.1 SE for Windows (StataCorp., College Station, TX, USA). Continuous data were first tested for normality with the Shapiro–Wilk test and graphically with quantile–quantile plots. If normally distributed, these data are presented as means ± SD or, if non-normally distributed, as medians with the interquartile range. Dichotomous data are expressed as numbers and percentages. Univariate comparisons were tested with Fisher's exact test or the chi-squared test for categorical variables. Student's unpaired *t*-test was used for continuous normally distributed variables or the Mann–Whitney' *U*-test for non-normally distributed data. The tests were performed two-sided, and a *P*-value of <0.05 was considered to be statistically significant.

RESULTS

In the investigated group of 716 patients operated upon within the last 6 years, no major adverse events, including death, stroke and cardiopulmonary depression, occurred during implantation and testing.

In 28 patients (3.8%), a DFT >21 J was noted with the initial shock configuration, which necessitated correction of the defibrillation system (study group). The mean age of these patients was 51 ± 14 years, ranging from 22 to 71 years (study group vs all patients, $P < 0.0009$). There were 20 male and eight female patients. The ejection fraction was 23.8 ± 11.8%. Twenty-four ICDs were implanted on the left and four on the right side. The failure rate of implanted devices on the right appeared to be significantly higher than that of devices being implanted on the left ($P = 0.02$). Demographic data are summarized in Table 1.

In 13 patients, the indication for ICD implantation was prophylactic according to the Multicenter Automatic Defibrillator Implantation Trial II (MADIT) criteria. The underlying diagnosis of dilated cardiomyopathy was found in 20 of the 28 patients, whereas the remaining eight patients suffered from ischaemic cardiomyopathy, i.e. there were significantly more cases of dilated cardiomyopathy in the study group ($P = 0.001$). Underlying diseases of the patients and indications for device implantation are summarized in Table 2.

Thirteen patients received a single chamber ventricular system; two of them presented with chronic atrial fibrillation. Twelve patients were provided with a duel chamber system; four of them suffered from sick sinus syndrome, four from

Table 1: Demographic data

Patients	Successful test ($n = 688$)	Failing initial shock ($n = 28$)	Significance
Age (years)			
Mean	60 ± 14	51 ± 14	$P = 0.0009$
Median	63	49	
Gender			
Male	550 (80%)	20 (71%)	$P = 0.336$
Female	138 (20%)	8 (29%)	
Ejection fraction (%)	27.4 ± 11.8	23.9 ± 11.8	$P = 0.124$
Implantation site			
Left	663 (96%)	24 (86%)	$P = 0.023$
Right	25 (4%)	4 (14%)	

Table 2: Underlying diseases and implantation indication

Patients	Successful test ($n = 688$)	Failing initial shock ($n = 28$)	Significance
DCM	250 (36.4%)	20 (71.5%)	$P = 0.001$
ICM	350 (50.9%)	8 (28.5%)	
Brugada	29 (4.2%)	0	
Long QT	16 (2.3%)	0	
HOCM	20 (2.8%)	0	
Other	23 (3.4%)	0	
Primary	490 (71.2%)	21 (75%)	$P = 0.83$
Secondary	198 (28.8%)	7 (25%)	n.s.

DCM: dilated cardiomyopathy; HOCM: hypertrophic obstructive cardiomyopathy; ICM: ischaemic cardiomyopathy; n.s.: not significant; other: amyloidosis, fibrosis; primary: primary prevention indication; secondary: secondary prevention indication.

intermittent atrial fibrillation, and two patients each from atrioventricular block II type Mobitz and atrioventricular block III, respectively. Three patients were treated with cardiac resynchronization therapy (CRT-D) due to additional left bundle branch block (Table 3). None of the patients received amiodarone at the time of implantation.

All 28 patients successfully reached a DFT ≤21 J and a safety margin of >10 J by changing the position of the ICD lead, replacing the device and/or optimizing the shock configuration (Table 4).

DISCUSSION

The discussion about whether or not to test a newly implanted ICD system has witnessed a renaissance during the last years, owing to improvements in ICD technology, including rapid onset and high energy supply. Yet, there is no evidence that even the highest energy supply with modern ICD devices permits the abandoning of intraoperative testing [4].

The prerequisite for an appropriate ICD function is the determination of the DFT or a safety margin of 10 J [7]. A further advantage of the testing procedure is the detection of ventricular arrhythmias (ventricular tachycardia and/or VF), as well as the analysis of lead function and system integrity to rule out the rare case of device failure [4]. Previous studies demonstrated an alarming rate of insufficient security in ICD patients when intraoperative testing was omitted [8]. In a study of 440 consecutive patients, Alter *et al.* reported inappropriate shocks in 12% of patients [9]. A first 20 J shock efficacy of 83%, i.e. a failure rate of 17%, was shown by Blatt *et al.* [5]. Christ *et al.* stated a shock failure rate of only 3%; however, with intraoperative corrections of the implanted system in 17% of their patients [10]. Only one study demonstrated no inappropriate shocks in their group of 42 patients assigned to intraoperative DFT testing, treated from 1995 to 1996. One may assume that the number of patients in that study was too small for a valid conclusion [6]. In our study, which was designed to include all consecutive patients (all comers), we found a first shock failure rate of 3.9%. It is noteworthy that 14% of these patients had their device implanted on the right side, which was significantly more than in the patient group with successful testing.

The probability of defibrillation is a statistical value in accordance with a dose–response curve. Testing of an ICD indicates a statistical probability of successful therapy. Multiple testing may

Table 3: Devices

Patients	Successful test (n = 688)	Failing initial shock (n = 28)	Significance
VVI	420 (61%)	13 (46%)	P = 0.16
DDD	179 (26%)	12 (43%)	P = 0.08
CRT	89 (13%)	3 (11%)	P = 1.00

CRT: resynchronization ICD; DDD: two-chamber ICD; VVI: one-chamber ICD.

Table 4: Intraoperative numbers and types of corrections and numbers of shocks applied intraoperatively

Age	Gender	ICD site	Lead reposition	Dual → single coil	Configuration	Device reposition	Total number of shocks
41	F	Left	1	1			5 (2)
53	M	Right	1	1			3 (1)
64	M	Left	1	1			5 (1)
60	M	Left	1				3 (1)
68	F	Left	2				5 (2)
49	M	Left	1				4 (2)
61	M	Left	1				3 (1)
22	M	Left	1	1	1	1	7 (3)
44	M	Left	1	1	1		5 (2)
54	M	Right	1	1			3 (1)
67	F	Left	1				3 (1)
38	M	Left	1				3 (1)
34	M	Left	3	1	1		6 (3)
70	M	Right	1				3 (1)
48	F	Left	1				3 (1)
49	F	Left	4	1	1	2	15 (7)
64	F	Right	2	1			7 (3)
43	M	Left	1	1			5 (2)
71	M	Left	1				3 (1)
50	M	Left	1				3 (1)
63	F	Left	1				3 (1)
47	M	Left	1	1	1		5 (2)
66	M	Left	2	1	2*	2	12 (6)
23	M	Left	1				3 (1)
24	F	Left	1	1			3 (1)
44	F	Left	2				5 (2)
48	M	Left	1				4 (3)
67	M	Left	1				3 (1)

The number of external defibrillations is given in parentheses. *Configuration changed to single coil and back to dual coil. Configuration indicates reversed polarity.

strain the probability of appropriate therapy, but an absolute security, i.e. a successful therapy in all cases, will remain unachievable. As the energy supply in the new generation of ICDs is rather rapid, myocardial ischaemia nowadays seems unlikely to be the reason for test failure. Shuger *et al*. demonstrated that prolonged procedure times and larger left ventricular diastolic diameters (>61 mm) were predictors of testing failure [11]. In our analysis, we also found a statistically significant shift towards dilated cardiomyopathy patients with regard to failed initial intraoperative testing ($P = 0.001$). Given that multiple testing, with repeat induction and consecutive cardioversions/defibrillations, for exact determination of the DFT also significantly burdens the patient, its usefulness can be questioned [12]. In 2002, the Low Energy Safety Study aimed at very low energy margins, but nearly half of their patients did not reach the safety margin of 10 J [13]. Thus, the aim of testing the safety margin primarily lowered the probability of retesting, as in our study. This fact, together with the aforementioned abandoned multiple testing for DFT, has been used as a strong argument against testing [14].

It is questionable whether there are clinical conditions in favour or against DFT testing and safety margin assessment.

Ventricular fibrillation can be induced by a T-wave shock or by burst stimulation, both of which lead to different characteristics of VF [15]. Moreover, induced and spontaneous episodes of VF are different, as are sustained and self-terminating episodes [16, 17]. Viskin and Rosse proposed that the decision concerning whether to test or not should be based on the characteristics of VF [14]. Given that arrhythmia may vary and that any ventricular arrhythmia should be terminated by adequate defibrillation, we do not recommend their suggestion [18].

Strickberger and Klein assumed an efficacy of about 5% when additional modifications of the implanted system are necessary to achieve an adequate DFT [3]. However, our system revisions after failed initial testing, which included lead repositioning, device relocation and alteration of the device configuration, were uniformly successful.

Atary *et al*. recommended refraining from intraoperative testing as a consequence of an adequate right ventricular threshold [19]. However, all our patients demonstrated adequate ventricular sensing of >6 mV and a pacing threshold of <1 V prior to testing. Thus, our data do not prove the hypothesis that the right ventricular stimulation threshold alone provides sufficient evidence for appropriate device function.

The main arguments against intraoperative testing are major adverse events, such as intractable VF, haemodynamic deterioration, neurological impairment and death [9, 20]. In a Canadian study population of 19 067 patients, death in association with defibrillator testing had a prevalence of 0.016%. Strokes have been observed in 0.026 and 0.5% of patients, respectively [9, 20]. In contrast, Healey *et al*. found no differences with regard to perioperative complications in patients having been tested or not [21]. In our total collective of 1512 patients treated from 1996 to date, we observed no strokes and no deaths related to intraoperative testing. We think that an adequate surgical implantation time, as well as strict adherence to the implantation protocol during surgery, especially concerning therapeutic procedures in the event of intractable VF, enhances the safety of a patient.

It has also been discussed that the majority of ICDs never treat ventricular arrhythmias and therefore do not need to be tested [14]. However, given that a significant survival benefit of primary ICD therapy has been shown [22, 23], appropriate testing seems important.

Three of the 28 patients who failed the initial intraoperative test had pacemaker leads implanted prior to the ICD implantation. These patients had their ICD implanted on the right side ($P = 0.02$). The reason for the initial testing failure in these three patients appears to be manifold. Devices implanted on the right side theoretically may not have an optimal shock vector and therefore might be prone to failure. None of the multiple studies has analysed the operating procedures, intraoperative testing and the outcome of patients being supplied with an ICD in the right pectoral region.

Amiodarone has been identified as a positive predictor for a DFT >25 J [8, 24]. Napp *et al*. especially recommended testing in young patients treated with amiodarone, but questioned the need for general intraoperative testing. None of our 28 patients was treated with amiodarone at the time of ICD implantation, but like in Napp's group, our patients who failed the initial intraoperative test were significantly younger on average [24].

CONCLUSION

The development of new ICD leads, shock algorithms, high-energy defibrillators and rapid energy supply has improved ICDs. Testing of ICDs is a safe and efficient procedure. Alterations of the implanted system, such as lead repositioning, device relocation and changing the device polarity, are effective means to achieve sufficient sensing and an appropriate safety margin to terminate life-threatening ventricular arrhythmias. The paradigm should not yet shift to elimination of ICD testing. Failure to test the DFT or failure to confirm safety margins is not the answer to improvement of ICDs.

Conflict of interest: none declared.

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