

## Observational Study

**Critical analysis of ineffective post implantation implantable cardioverter-defibrillator-testing**

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**Abstract****AIM**

To test if the implantable-cardioverter-defibrillator is done at the time of implantation. We investigate if any testing should be performed.

**METHODS**

All consecutive patients between January 2006 and December 2008 undergoing implantable cardioverter-defibrillator (ICD) implantation/replacement (a total of 634 patients) were included in the retrospective study.

**RESULTS**

Sixteen patients (2.5%) were not tested (9 with LA/LV-thrombus, 7 due to operator's decision). Analyzed were 618 patients [76% men, 66.4 ± 11 years, 24% secondary prevention (SP), 46% with left ventricular ejection fraction (LVEF) < 20%, 56% had coronary artery disease (CAD)] undergoing defibrillation safety testing (SMT) with an energy of 21 ± 2.3 J. In 22/618 patients (3.6%) induced ventricular fibrillation (VF) could not be terminated with maximum energy of the ICD. Six of those (27%) had successful SMT after system modification or shock lead repositioning, 14 patients (64%) received a subcutaneous electrode array. Younger age ( $P = 0.0003$ ), non-CAD ( $P = 0.007$ ) and VF as index event for SP ( $P = 0.05$ ) were associated with a higher incidence of ineffective SMT. LVEF < 20% and incomplete revascularisation in patients with CAD had no impact on SMT.

**CONCLUSION**

Defibrillation testing is well-tolerated. An ineffective SMT occurred in 4% and two third of those needed implantation of a subcutaneous electrode array to pass

a SMT > 10 J.

**Key words:** Implantable cardioverter defibrillator; Implantable cardioverter-defibrillator; Sudden cardiac death; Defibrillation test; Safety margin test; Ventricular fibrillation; Subcutaneous electrode array

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**Core tip:** The implantable cardioverter defibrillator is crucial for primary and secondary prevention of severe life-threatening ventricular tachyarrhythmia. However the importance concerning intra-operative defibrillation testing and clinical relevance of inadequate testing of implantable cardioverter-defibrillator (ICD) devices remains still under debate. In this study, we analyzed our single-center data of patients undergoing ICD implantation or replacement to determine the number of failed internal defibrillation testing at the time of ICD implantation and the consequences for management. We critically reflect the progressive trend to omit defibrillation testing at the time of ICD placement.

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## INTRODUCTION

The implantable cardioverter defibrillator (ICD) is widely accepted for primary<sup>[1,2]</sup> and secondary prevention<sup>[3,4]</sup> of severe life-threatening ventricular tachyarrhythmia. The Heart Rhythm Society updated appropriate use criteria for ICD therapy<sup>[5]</sup>, however the importance concerning intra-operative defibrillation testing and clinical relevance of inadequate testing of ICD devices remains still under debate<sup>[6-10]</sup>.

One limitation of recent observational studies is a bias against testing in patients with more severe illness who are felt to be at increased risk for complications during intra-operative defibrillation testing<sup>[11-14]</sup>. Although severely impaired left ventricular function predicts higher intra-operative defibrillation threshold<sup>[8,15,16]</sup>, patient with lower left ventricular ejection fraction (LVEF) are less likely<sup>[11-14]</sup> or even excluded<sup>[17]</sup> to undergo intra-operative defibrillation testing. Furthermore, severe, non revascularized coronary artery disease (CAD) is described as an absolute or relative contraindication for intra-operative defibrillation testing<sup>[15,18,19]</sup> and were less likely to undergo such testing in recent studies<sup>[12,14,16,19]</sup> although these patients would probably benefit most from an adequate defibrillation threshold.

We analyzed all consecutive patients between January 2006 and December 2008 undergoing ICD im-

plantation or replacement to determine the number of failed internal defibrillation testing at the time of ICD implantation and the consequences for management. Our study extends the existing literature by also including patients excluded in previous studies. We critically reflect the progressive trend to omit defibrillation testing at the time of ICD placement<sup>[9,10,14]</sup>.

## MATERIALS AND METHODS

All consecutive patients undergoing initial ICD implantation or generator replacement from January 2006 to December 2008 were analyzed in this retrospective, single-center analysis.

Devices of all 4 important international companies were implanted. They were implanted in the catheter laboratory by 5 experienced cardiologists. In all patients, adequate ventricular sensing (> 9 mV) and pacing threshold (< 1 V) was confirmed. In the absence of absolute contraindications [e.g., left atrial appendage (LAA) or left ventricular (LV) thrombus], intra-operative ICD testing was routinely performed to confirm correct sensing, processing, shock delivery and termination of T-wave shock-induced VF. Our protocol for intra-operative ICD testing required at least one induction of VF with successful first shock terminating VF at a safety margin of at least 10 Joule (J) below the maximum output of the implanted device. If the first shock was not successful, a second shock at the maximum output of the device was delivered. In case this shock was still not successful, external defibrillation with a 360 J biphasic shock was performed. Patients with the need of a second shock at the maximum output or external defibrillation in order to terminate VF were considered as ineffective safety margin testing (SMT) and were included in our study. Further management of these patients included intra-operative right ventricular lead reposition or ICD-system modification such as addition or subtraction of the superior vena cava (SVC) shock coil and polarity reversal, respectively. In case the SMT was still ineffective, the implantation of a subcutaneous electrode array, considered to be the most effective method for reducing defibrillation threshold<sup>[20]</sup>, was planned.

Clinical characteristics, the consecutive management of pts with ineffective SMT and follow up data were explored by reviewing the medical records. Biplane left ventricular ejection fraction (LVEF) was derived by echocardiography and all measurements were done or supervised independently by an experienced cardiologist specialized in echocardiography. According to our center's standard practice, all patients underwent coronary angiography prior to ICD placement, ascertaining a definite coronary status. The implanted subcutaneous electrode array was solely a Medtronic 6996SQ.

## Statistical analysis

Descriptive data were reported as frequencies, means and standard deviations or median and interquartile

range, respectively. Two-sided *t*-tests for independent samples were used for continuous variables.  $\chi^2$  analysis was used to compare categorical variables and one-way analysis of variance (ANOVA) was used to compare continuous variables. All statistics were computed with SPSS software (SPSS Inc, Chicago, Illinois). All probability values are 2-sided, with values of  $< 0.05$  considered significant.

## RESULTS

### *Patient characteristics*

From 634 analyzed patients, 16 (2.5%) had no intra-operative defibrillation testing (9 patients (1.4%) due to LV- or LAA-thrombus and 7 (1.1%) due to decision of the operator (mainly atrial fibrillation with ineffective oral anticoagulation). Included in this retrospective analysis were 618 consecutive patients who received defibrillation testing after transvenous ICD implantation or ICD replacement. The population is described in Table 1. LVEF was  $\leq 20\%$  in 284 patients (46%). The indications for ICD placement included primary (76%) as well as secondary prevention (24%). The index arrhythmia for secondary prevention was sustained ventricular tachycardia (VT) in 72% and ventricular fibrillation (VF) in 28%, respectively. Patients with coronary artery disease (CAD) were further divided in those completely revascularized (56%) and those with residual significant stenoses  $> 70\%$  or a central occluded main vessel, respectively (29% and 15%, respectively). Further on we distinguished whether one (36%) or more than one main vessel (8%) was not completely revascularized. Patients with the diagnosis of a non-ischemic cardiomyopathy were subdivided whether they suffered from post myocarditis dilated cardiomyopathy (DCM) or from other types of cardiomyopathy (e.g., ARVD, LV non-compaction, HOCM, primary channelopathy).

### *Results of intra-operative defibrillation testing*

Effective defibrillation SMT was performed in 596 patients (96.4%) with a mean energy of  $20.8 \pm 2.3$  J. In 22 patients (3.6%) induced VF could only be terminated with the maximum energy of the implanted device or with an external defibrillation (Table 1). There were no severe complications (death, major or minor strokes or cardiogenic shock) in any of the 618 SMT performed.

In 22 patients (3.6%) a  $> 10$  J SMT could not be achieved intra-operatively with the initial ICD configuration. The patients with ineffective SMT were younger ( $P = 0.003$ ), and in univariate analysis they were less likely to have CAD as underlying diagnosis ( $P = 0.007$ ) or VT as the index arrhythmia ( $P = 0.05$ ) for secondary ICD indication (Table 1).

Variables without impact on the efficiency of SMT in univariate analysis included whether or not patients had a LVEF  $< 20\%$ , had a secondary preventive indication for ICD, were incompletely revascularized, had more than one main coronary vessel significantly diseased and were

taking amiodarone, respectively (Table 1).

### *Management of patients with ineffective initial SMT*

The characteristics of the patients with ineffective SMT are depicted in Table 2. One or more of the following system modifications were initiated: Reprogramming the defibrillation polarity in 21 and deactivation of the SVC shock coil in 19 patients as well as repositioning the right ventricular lead in 12 patients. Six patients (27%) passed subsequent SMT, 16 patients had still ineffective SMT and were planned for a subcutaneous electrode array. Two patients refused further procedures and in the remaining 14 patients an adequate SMT  $> 10$  J was documented post implantation of a subcutaneous electrode array.

### *Tachyarrhythmia events during follow up*

The mean follow up was  $23.6 (+21)$  mo for patients with initially effective SMT and  $15.8 (+21)$  mo for those with initially ineffective SMT. Antiarrhythmic medication was equally balanced between both groups (Table 3). In general, there were significantly more events in patients with CAD (19.6%) compared to patients with non CAD (12.1%)  $P = 0.02$ . There was a trend towards more events in patients with secondary prophylactic ICD indication ( $P = 0.08$ ). No death or resuscitation occurred during the follow-up period, and 124/530 patients (23.4%) with initial effective SMT and 2/22 patients (9.1%) with initially ineffective SMT ( $P = 0.02$ ) experienced tachyarrhythmia events (Table 3).

## DISCUSSION

We analyzed a very large population undergoing intra-operative ICD defibrillation testing<sup>[6]</sup>, including a significant group of patients (284 patients, 46% of total) with an LVEF  $< 20\%$ , a patient group that was unlikely undergoing intra-operative ICD testing<sup>[11-14,16]</sup> or was even excluded from former studies<sup>[17]</sup>.

Our data show several important findings: (1) Ineffective SMT occurred in roughly 4% of ICD implantations. Despite ICD-System reprogramming as well as RV shock lead repositioning, two thirds of those required implantation of a subcutaneous electrode array to pass a SMT  $> 10$  J; (2) SMT can be performed safely and without major complications, even in patients with an LVEF  $< 20\%$ . There was no impact on the efficacy of SMT compared to patients with an LVEF  $> 20\%$ ; (3) Severe coronary 2 or 3 vessel disease with residual significantly stenosed/occluded main vessels showed no impact on safety and efficacy of SMT; and (4) The percentage of patients who are unsuitable for intra-operative defibrillation testing is small (2.5% of our study population).

### *Ineffective intra-operative safety margin testing*

Despite advancements during the last years in ICD systems and lead technology resulting in enhanced defibrillation efficacy, 4% in our patient population failed to

**Table 1** Baseline characteristics

	All	Effective SMT	Ineffective SMT	P-value
Number, <i>n</i> (%)	618	596 (96.3)	22 (3.7)	
Sex				
Male, <i>n</i>	470	452	18	
Female, <i>n</i>	148	144	4	
Age (years)				
Mean ( $\pm$ SD)	66.4 ( $\pm$ 11)	66.7 ( $\pm$ 10.6)	54.6 ( $\pm$ 16.5)	<i>P</i> = 0.0003
Median (IQR)	69 (60-74)	69 (62-74)	54 (41-69)	
LVEF (%)				
Mean ( $\pm$ SD)	31 ( $\pm$ 12.4)	31 ( $\pm$ 12.5)	26.9 ( $\pm$ 9.0)	<i>P</i> = n.s.
Median (IQR)	30 (22-35)	30 (23-35)	30 (20-35)	
LVEF > 30%, <i>n</i> (%)	248 (40.1)	240 (36.9)	8 (3.2)	
LVEF < 30%, <i>n</i> (%)	370 (59.9)	356 (56.1)	14 (3.8)	<i>P</i> = n.s. (> 30% vs < 30%)
LVEF > 20%, <i>n</i> (%)	334 (54.0)	320 (49.8)	14 (4.2)	
LVEF < 20%, <i>n</i> (%)	284 (46)	276 (43.2)	8 (2.8)	<i>P</i> = n.s. (> 20% vs < 20%)
BMI (kg/m <sup>2</sup> )				
Mean ( $\pm$ SD)	28.4 ( $\pm$ 4.7)	28 ( $\pm$ 4.7)	29 ( $\pm$ 4.0)	<i>P</i> = n.s.
Median (IQR)	28 (17-28)	28 (25-31)	29 (25.5-33)	
Indication				
Primary prevention, <i>n</i> (%)	468 (76)	452 (72.6)	16 (3.4)	
Secondary prevention, <i>n</i> (%)	150 (24)	144 (20)	6 (4.0)	<i>P</i> = n.s. (pp vs sp)
Type of arrhythmia for secondary prevention, <i>n</i> (%)				
Sustained VT	108 (72)	106 (70.1)	2 (1.9)	
VF	42 (28)	38 (18.1)	4 (9.5)	<i>P</i> = 0.05 (VT vs VF)
SMT-Energy (J)				
Mean ( $\pm$ SD)	21 ( $\pm$ 2.3)	20.8 ( $\pm$ 2.3)	30.9 ( $\pm$ 2.0)	
Median (IQR)	20 (20-22)	20 (20-20)	30 (30-30)	
Diagnosis				
Non CAD, <i>n</i> (%)	270	254 (94.1)	16 (5.9)	
DCM (myocarditis), <i>n</i> (%)	232 (85)	218 (79)	14 (6.0)	
Other CM (non myocarditis), <i>n</i> (%)	38 (15)	36 (9.8)	2 (5.2)	
CAD, <i>n</i> (%)	348	342 (98.3)	6 (1.7)	<i>P</i> = 0.007 (nonCAD vs CAD)
Complete revascularized, <i>n</i> (%)	196 (56)	192 (54)	4 (2.0)	
Not complete revascularized, <i>n</i> (%)	152 (44)	150 (42.7)	2 (1.3)	<i>P</i> = n.s. (complete vs in-complete revascularized)
One vessel disease	124 (81.6)	122 (80.0)	2 (1.6)	
> One vessel disease	28 (18.4)	28 (18.4)	0 (0)	<i>P</i> = n.s. (one vessel vs > one)
Stenosed	100 (65.8)	100 (65.8)	0 (0)	
Occluded	52 (34.2)	50 (30.4)	2 (3.8)	<i>P</i> = n.s. (stenosed vs occluded)
Medication				
Amiodaron medication, <i>n</i> (%)	124 (20)	118 (15.2)	6 (4.8)	
No amiodaron, <i>n</i> (%)	494 (80)	478 (76.8)	16 (3.2)	<i>P</i> = n.s. (amio vs no amio)

SMT: Safety margin test; *n*: Number; SD: Standard deviation; IQR: Interquartile range; LVEF: Left ventricular ejection fraction; BMI: Body mass index; pp: Primary prevention; sp: Secondary prevention; VT: Ventricular tachycardia; VF: Ventricular fibrillation; CAD: Coronary artery disease; DCM: Dilated cardiomyopathy; CM: Cardiomyopathy; amio: Amiodarone; n.s.: Not significant; n/a: Not applicable.

achieve the conventional SMT > 10 J. This in line with similar findings of 6%-7% insufficient SMT in older retrospective studies<sup>[11,16]</sup> using less sophisticated ICD-systems, suggesting that an adequate defibrillation threshold is not only dependent on the implanted ICD-system. Russo *et al.*<sup>[16]</sup> found that simply changing to a high output ICD-system to pass an initially insufficient SMT was not enough in 48% of patients. This further highlights the fact that an SMT < 10 J exhibits a more complex problem than just deliver higher shock energy<sup>[9]</sup> and that individual measures have to be taken to reach an acceptable SMT > 10 J. According to our data and in line with previous findings, VF as the index arrhythmia for ICD implantation, the diagnose of a non-ischemic cardiomyopathy and younger age were associated with a higher incidence of ineffective SMT. However, none of these predictors helped to identify the 22 patients of our study who failed to pass

a SMT > 10 J (Table 2). In line with previous findings<sup>[12,16]</sup>, our study revealed that still two third of patients after ICD system modification and RV lead replacement required further measures to reach a subsequent SMT > 10 J. In our study, we implanted a subcutaneous electrode array, a measure that is considered to be the most effective for reducing defibrillation threshold<sup>[15]</sup>. Inconsistent evidence exists regarding long term outcome of patients who do not meet an intra-operative SMT > 10 J<sup>[6,7,18]</sup> or where not tested at all<sup>[9,10]</sup>.

On the other side, the HRS/EHRA/APHS/SOLACE expert consensus statement on ICD programming and testing<sup>[21]</sup> states with a Class IIa recommendation, "that it is reasonable to omit defibrillation testing in patients undergoing initial left pectoral transvenous ICD implantation procedures where appropriate sensing, pacing and impedance values with fluoroscopically

**Table 2** Characteristics of patients with failed intra-operative safety margin test

<i>n</i>	Age at time of implantation (years)	Sex (m/f)	Indication for ICD implantation	LVEF (%)	Primary vs secondary ICD indication	Further management after failed initial SMT
1	46	m	LAD stenosed	30	pp	Subcutaneous array
2	45	w	oCM	15	pp	PDT OK
3	74	w	oCM	36	pp	Subcutaneous array
4	41	m	cmpl revasc	39	pp	Subcutaneous array
5	54	w	DCM	10	pp	Subcutaneous array
6	25	m	oCM	20	sp	Subcutaneous array
7	68	m	DCM	35	sp	Subcutaneous array
8	69	m	RCA occluded	31	sp	PDT OK
9	73	m	oCM	30	pp	PDT OK
10	37	m	TGV surgery	30	pp	Subcutaneous array
11	69	m	DCM	20	pp	none
12	46	m	LAD stenosed	30	pp	Subcutaneous array
13	45	w	DCM	15	pp	PDT OK
14	74	w	DCM	36	pp	Subcutaneous array
15	41	m	cmpl revasc	39	pp	Subcutaneous array
16	54	w	DCM	10	pp	Subcutaneous array
17	25	m	DCM	20	sp	Subcutaneous array
18	68	m	DCM	35	sp	Subcutaneous array
19	69	m	RCA occluded	31	sp	PDT OK
20	73	m	DCM	30	pp	PDT OK
21	37	m	vs D surgery	30	pp	Subcutaneous array
22	69	m	DCM	20	pp	None

m: Male; w: Women; ICD: Internal cardioverter defibrillator; LAD: Left anterior descending coronary artery; oCM: Other cardiomyopathy; cplm revasc: Complete revascularized; RCA: Right coronary artery; TGV: Transposition of the great vessels; VSD: Ventricular septum defect.

**Table 3** Follow up

		All	Effective SMT	Ineffective SMT	<i>P</i> -value
FU, <i>n</i> (%)		552 (89.3)	530 (96)	22 (100)	
FU duration (mo)	Mean (± SD)	21.1 (± 21)	21.5 (± 21)	15.8 (± 21)	<i>P</i> = n.s.
Antiarrhythmica, <i>n</i> (%)					
	Amiodarone		122 (23.0)	6 (27)	<i>P</i> = n.s.
	Sotalol		2 (0.4)	0 (0)	<i>P</i> = n.s.
	β-blocker		485 (91.5)	20 (91)	<i>P</i> = n.s.
Events during FU, <i>n</i> (%)			124 (23.4)	2 (9.1)	<i>P</i> = 0.02
	Inadequate therapy		4 (0.8)	2 (9.1)	<i>P</i> = n.s.
	ATP		58 (10.9)	0 (0)	
	Shock delivery		36 (6.8)	0 (0)	
	ATP and shock delivery		20 (3.8)	0 (0)	
	VT ablation		6 (1.1)	0 (0)	

FU: Follow up; ATP: Anti tachycardia pacing; n.s.: Not significant.

well-positioned RV leads". Furthermore, with a class IIa recommendation the expert consensus state "that defibrillation testing is reasonable in patients undergoing a right pectoral transvenous ICD implantation or ICD pulse generator changes".

For the arguments mentioned above we recommend that a decision to perform intraoperative testing during ICD placement without absolute contraindication should be taken case-by-case. Our data suggest that the intraoperative testing should be considered for patients who are younger, patients with non-CAD as underlying disease and VF as the index arrhythmia for secondary ICD indication. Furthermore patients with HCM, special conditions such as severe obesity, amiodarone use and right pectoral implants as well as pre-existing

RIATA (SJM) leads should be considered to be tested intraoperatively.

### **Rationale for intra-operative defibrillation testing**

Up to 65% of implantation procedures are performed without any induction test<sup>[6,14]</sup>. Patients less likely to be tested were sicker and therefore more likely to have adverse outcomes, including death<sup>[6,11,13,16]</sup>. The strength of our study is that intra-operative testing was done in 97.5% of all consecutive patients. In contrast to former studies<sup>[11-13,16]</sup> we could show that testing the ICD at the time of placement is safe and effective, even if sicker patients (e.g., LVEF < 20% and severe, non revascularized coronary 2 or 3 vessel disease) were included. Newer ICD systems with advancements in



defibrillator and lead technology and resulting enhanced defibrillation efficacy may be one reason for this finding. Nevertheless, 22 patients (4%) of our study population had an ineffective intra-operative SMT and would have been missed without consequently passing all patients without a clear contraindication through an intra-operative defibrillation test. Even if only a small fraction of patients could potentially benefit from a SMT at ICD-implantation, it poses a forensic issue to prove at least once device efficacy in adequate sensing, computing and termination of VF. In our study, 14/22 patients needed the implantation of a subcutaneous electrode array to achieve adequate DFTs. Although several reasons imply that long term survival may not necessarily be affected whether or not defibrillation testing is done<sup>[6,9,10,18]</sup>, one study suggested that not having a defibrillation test was an independent risk factor of SCD even if sicker patients were the ones not tested<sup>[11]</sup>. However, no study so far was sufficiently powered to establish equivalence or superiority of a strategy of no testing vs SMT at the time of ICD placement as Strickberger *et al.*<sup>[22]</sup> calculated a sample size of approximately 29000 patients that would need to be randomized in a mortality study to achieve definite conclusions on this question with an adequate statistical power.

Two recently published randomised studies showed that defibrillation testing at the time of ICD implantation does not appear to predict total mortality<sup>[9,10]</sup>. But still it remain legal and regulatory considerations: The labelling on all ICD's recommend an assessment of defibrillation efficacy at implant not least to document the defibrillation behaviour with new drugs and the integrity of new ICD systems coming to the market.

For the reasons mentioned above and underlined with the finding of our study, we conclude that defibrillation testing remains an important part of ICD placement and the decision to perform or omit testing should be taken case-by-case.

In conclusion, in the absence of sufficiently powered studies evaluating long term outcome of patients with an ineffective intra-operative defibrillation testing, our findings underline that routine SMT still remains an important part of ICD placement. An ineffective SMT occurs in about 4% of patients, and even after ICD system modification and RV shock lead repositioning three quarter of those need implantation of a subcutaneous electrode array to pass a SMT > 10 J.

## COMMENTS

### Background

The implantable cardioverter defibrillator (ICD) is widely accepted for primary and secondary prevention of severe life-threatening ventricular tachyarrhythmia. However the importance concerning defibrillation testing at the time of implantation and clinical relevance of inadequate testing of ICD devices still remains under debate.

### Research frontiers

Defibrillation testing was done at the time of implantation in randomized trial investigating the efficacy of ICD therapy. They critically reflect the progressive

trend to omit defibrillation testing at the time of ICD placement.

### Innovations and breakthroughs

Two recently published randomised studies showed that ICD implantation without defibrillation testing is non-inferior to implantation with testing. Although one of these studies included 2500 patients, it is still underpowered to address the question of future shock efficacy or reduction of arrhythmogenic death. The authors' study present a large cohort of patients undergoing ICD-implantation and showed that in 4% of the patients the ICD did not terminate induced VT during intraoperative testing. Furthermore their data suggested that intraoperative testing of the ICD is a well-tolerated procedure.

### Applications

The data of their study showed that intraoperative ICD-testing lead in a not negligible percentage of patients to a system modification or even a subcutaneous array implantation to prove correct detection and termination of induced ventricular fibrillation at the time of ICD-implantation.

### Terminology

ICD are routinely implanted since 30 years to prevent sudden cardiac death. The detection of a life-threatening ventricular arrhythmia leads to a biphasic high energy 30-40 J impulse between the RV-coil and the subscapular located aggregate to terminate the arrhythmia. Testing the correct detection and termination of induced ventricular fibrillation at the time of ICD implantation is included as a recommendation in product labels.

### Peer-review

This is a well-written paper.

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