Pre-hospital discharge testing after implantable cardioverter defibrillator implantation: A measure of safety or out of date? A retrospective analysis of 975 patients

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Aims
The present study evaluates the relevance and additional safety value of pre-hospital discharge (PHD) testing in patients with implantable cardioverter defibrillator (ICD) therapy.

Methods
From June 1998 to May 2009, 975 patients (830 male, 145 female) with ICD were screened retrospectively for failed PHD and analysed for its consequences, risk factors, and patient characteristics after successful intra-operative testing in the implantation procedure.

Results
Pre-hospital discharge testing procedure was performed in 809 cases. No serious adverse events (e.g. death, persistent ventricular fibrillation or ventricular tachycardia, stroke) occurred. The overall incidence of failed PHD was 1.4% (n = 11). The underlying mechanisms were defibrillation threshold failure in 9/11 cases and sensing failure in 2/11 cases.

Conclusions
In this study predictors for PHD-failure are: (i) cardiomyopathy other than ischaemic or dilative, (ii) young age, and (iii) small or very large left ventricular end-diastolic diameter (<40 or >65 mm). Particularly, (i) manufacture of device or leads, (ii) lead design, (iii) medical treatment, or (iv) gender have no significant influence on PHD failure.

Keywords
Defibrillation • Electrophysiology tests • ICD

Introduction
In recent years, various multi-centre prospective studies have shown a benefit in survival after implantable cardioverter defibrillator (ICD) therapy in patients who are considered to be at high risk of sudden arrhythmic death such as impaired left ventricular function or other cardiac diseases, for example Brugadás syndrome, long QT syndrome, or arrhythmogenic right ventricular dysplasia (ARVD).1-5 The current guidelines of the European and American Cardiac Societies contain clear evidence-based recommendations in the use of ICD therapy.6-9 However, no clear recommendations exist on the implantation protocols concerning intra- and peri-operative defibrillation threshold testing (DFT). From a historical perspective intra-operative and pre-hospital discharge (PHD) testing were useful tools to affirm an accurate ICD function.10-13 It seems in today’s clinical practice that PHD testing is dispensable. Safety data are rare about this widely accepted strategy to discharge the patient without a PHD.11 Nevertheless, we are faced with a very heterogeneous patient group treated with ICD devices, e.g. ischaemic and dilated cardiomyopathy on the one side and long QT, hypertrophic cardiomyopathy or Brugada syndromes on the other. Currently, it is not clear as to whether such different patient groups need different safety strategies in ICD therapy.14-16 Additionally, some of the
manufacturers describe a detailed testing procedure in the manuals that is part of the certification and is legally binding.

Accurate and effective ICD function depends on a correct sensing of intracardiac electrical activity, appropriate interpretation by the device, and an effective shock delivery. Lead-related complications e.g. sensing failure, lead dislocations or increased thresholds are common problems in the first days after ICD implantation.

This retrospective study evaluates the additional benefit of a PHD testing 2–3 days after implantation with regard to safety and effectiveness in a large patient population. Our data characterize the risk of ineffective PHD (sensing or defibrillation threshold failure) and define a patient group with increased risk of an ineffective ICD testing in the PHD setting.

Materials and methods

Patient population and implantable cardioverter defibrillator testing

Between June 1998 and June 2009, 975 consecutive patients undergoing ICD implantation or lead revision (pace/sense or shock lead) were included in this retrospective, single-centre analysis. The safety margin method with two independent ventricular fibrillation (VF) inductions for the DFT was applied to verify the ICD function. In the absence of contraindications, an intra-operative ICD testing was routinely performed in \( n = 809 \) patients to confirm a correct sensing, processing, and shock delivery with the required safety margin of 10 J or more. An additional PHD testing 2 or 3 days after implantation was accomplished. For confirmation of correct ICD function VF was induced by T-wave shock or high-frequency (HF) burst (40/50 Hz). A safety margin of 10 J was required and the second internal shock was programmed with maximal output of the device. An upper limit of vulnerability (ULV) testing was not performed.

The standard procedure for ICD implantation and testing is described in Figure 1.

Contraindications for ICD testing were defined as thrombotic formations in the left atrium or left ventricle, haemodynamic instability, spontaneous VF, or ventricular tachycardia (VT), severe device-associated complications (pneumothoraces, pericardial effusion) or acute coronary syndromes. Therefore, in 147 cases the device could not be tested. In another 19 cases, a sustained VF or fast VT was not inducible despite all available stimulation algorithms including T-wave-shock, 40/50 Hz burst or HF stimulation.

The mean age of the study population at baseline was 62.6 ± 11.3 years with a median of 65.5 [56.2–70.6] years. 830 patients were men, 145 patients were women. Left ventricular ejection fraction (LVEF) at the time of implantation was 29.8 ± 11.9% with a median of 25% [20–35]. 544 patients had an ischaemic, 358 patients had a dilated cardiomyopathy, and 73 patients suffered from other arrhythmogenic diseases. 612 (62.7%) patients had ICD therapy for primary prophylaxis of sudden cardiac death (SCD), 363 (37.3%) received an ICD for secondary prophylaxis of SCD.

Detailed patient characteristics at the time of implantation are shown in Table 1.

Table 1

<table>
<thead>
<tr>
<th>Category</th>
<th>Count (n)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex: Male</td>
<td>830</td>
<td>100%</td>
</tr>
<tr>
<td>Sex: Female</td>
<td>145</td>
<td>17.9%</td>
</tr>
<tr>
<td>Age, mean ± SD (years)</td>
<td>62.6 ± 11.3</td>
<td>65.5 [56.2–70.6]</td>
</tr>
<tr>
<td>LVEF, mean ± SD (%)</td>
<td>29.8 ± 11.9</td>
<td>25% [20–35]</td>
</tr>
<tr>
<td>VT/VF: Primary prophylaxis</td>
<td>612</td>
<td>62.7%</td>
</tr>
<tr>
<td>VT/VF: Secondary prophylaxis</td>
<td>363</td>
<td>37.3%</td>
</tr>
</tbody>
</table>

Pharmacological treatment at time of implantation and pre-hospital discharge

The antiarrhythmic treatment of the study group at time of implantation included beta blockers (75%), sotalol (5%), amiodaron (35%), digoxin (35%), and class lc antiarrhythmics (7%). Angiotensin-converting enzyme/AT 1 blockers (85%) and diuretics (62%) were applied as a treatment for chronic heart failure.

Devices and leads

In this study, current ICD devices and leads of the following companies were implanted. (i) Biotronik (Berlin, Germany; \( n = 190 \)), (ii) CPI/Guidant/Boston Scientific (Natica, USA; \( n = 445 \)), (iii) ELA (Cedex, France; \( n = 2 \)), (iv) Medtronic (Minneapolis, USA, \( n = 337 \)), and (v) St Jude Medical (St Paul, USA; \( n = 1 \)).

Single-chamber ICDs were implanted in \( n = 522 \) cases and dual-chamber ICDs were used in \( n = 235 \) patients. Two hundred and seventeen patients received a biventricular ICD. Technical details of the implanted ICDs and leads are summarized in Table 2.

Statistical analysis

All data and statistics are reported as mean ± standard deviation (m ± sd) for continuous normally distributed data or as median (25–75%) for not normally distributed variables, respectively. For the comparisons between normally distributed variables, the paired t-test (modified by Welch for non-equal variance) was used. Non-normally distributed data were analysed using the Mann–Whitney U-test. Categorical variables are shown as number (%) and \( \chi^2 \)-test was applied. Logistic regression was applied for multi-variate analyses. \( P \) values below 0.05 were considered significant.

Results

In 809 cases with intra-operative ICD test seven failed DFT tests were registered, despite lead repositioning and high-energy (HE) device implantation. These patients need further revision as described in Figure 1.

There were no severe complications e.g. death, major or minor strokes, therapy-refractory VF or cardiogenic shock in any of the 783 PHD tests performed. Minor side effects of propofol-sedation e.g. transient hypotension or respiratory depression were registered in 32 patients and were treated with fluid infusion and/or non-invasive ventilation.

Efficacy and additional value of pre-hospital discharge testing

In 166 of 975 patients intra-operative DFT and PHD testing were not performed because of contraindications. In 19 cases persistent VT/VF could not be achieved with T-wave shock and HF burst.

During implantation procedure a group of 783 patients without any contraindications received successful intra-operative DFT testing with a safety margin of at least 10 J. A small number of patients (\( n = 7 \)) had an ineffective intra-operative testing. An internal termination of induced VF was not possible despite lead repositioning or other technical efforts.
Two to three days after the implantation procedure a PHD testing was performed in 783 patients. 11 patients (1.1%) failed PHD testing despite the prior effective intra-operative testing. Defibrillation threshold testing failures are shown in Table 3.

There were significant differences in patients' characteristics with failed PHD compared with the study population. The following characteristics had statistical significance for a PHD failure: (i) younger age at the time of implantation (mean: 50.1 years, median: 46.6 years vs. mean: 62.6, median: 65.5 years) ($P = 0.019$), (ii) cardiac diseases other than ischaemic and dilated cardiomyopathy ($P = 0.049$), and (iii) patients with very small or very large left ventricular end-diastolic diameter (LVEDD < 40 or > 65 mm) ($P = 0.001$). All patients with failed PHD were men.

### Reasons for pre-hospital discharge failure and solutions

All 11 patients with insufficient PHD testing had a prior effective intra-operative testing. The main part ($n = 9$) was due to DFT failure, in two cases a sensing failure of VF was documented. In all cases macrodislocations of the participating leads were excluded (chest X-ray and/or fluoroscopy). One patient (No. 11) with sensing failure did not have any ventricular rhythm without stimulation caused by a third-degree atrio-ventricular block. Sensing testing was not possible.

The problem of DFT failure was solved by programming a reversed shock polarity ($n = 2$), lead replacement ($n = 5$), implantation of a Sub Q array ($n = 5$), and implantation of a high-
energy device (n = 2). In these nine cases of DFT failure a combination of two interventions in three procedures (Sub Q array + high-energy device) and of three interventions (Sub Q array + high-energy device + reversed polarity) were necessary to terminate VF. The two cases of sensing failure underwent lead revision.

**Influence of manufacturer, lead characteristics, and lead position**

There was no difference of DFT efficacy between the ICD models manufactured by Biotronik, Boston Scientific/Guidant/CPI, and Medtronic. For other devices, e.g. ELA Medical and St. Jude, there are no valid data evaluated in this study. We did not find any significant difference for efficacy of DFT in relation to different lead types (true bipolar vs. integrated bipolar, single- vs. dual-shock coil) and lead position (apical vs. septal vs. basal). All included ICD systems used ‘hot can’ technology.

**Influence of medical treatment at the time of implantation/pre-hospital discharge testing**

We did not find any significant influence of pharmacological treatment as a predictor for PHD failure.

**Discussion**

The present study was performed to analyse a large cohort of 975 ICD patients for the additional value of PHD testing regarding safety aspects and effectiveness of ICD therapy and its complications.

The current guidelines do not contain a highly standardized protocol for implantation procedure and peri-operative ICD testing. Defibrillation threshold testing and sensing tests in VF after its artificial induction (high-frequency burst or T-wave shock) were used as a gold standard to guarantee a safe and effective ICD function in malignant tachyarrhythmias17,18 or to verify alternative approaches such as ULV testing.19 The procedure of DFT testing is not consequently performed in clinical practice due to its uncertain additional value and its potential risks. In addition, there is no uniform standard for testing the minimal or the sufficient energy level for a safe termination of VF.

Our study demonstrates that the safety margin method with two independent VF inductions is a time-consuming procedure but with an additional safety profit for selected patient groups. Pre-hospital discharge testing is sufficient to confirm an effective ICD function (sensing, signal processing, and DFT) early after implantation. Pre-hospital discharge procedure does not increase the peri-procedural complication rate. Furthermore, ICD therapy failure in PHD is rare (1.4%) after successful intra-operative DFT test. Ineffective ICD therapy is caused by DFT failure in most of the cases (9/11). The rate of sensing failure is very low (2/11). In detail our data define a specific patient population that is different from the majority of ICD patient groups with coronary heart disease or dilative cardiomyopathy. The risk population for failed PHD has younger age, small or very large left ventricular diameters and heart diseases other than aforementioned.

Following these data, we have to deal with the controversy that the named population has a better prognosis for surveillance and a better quality of life than patients with dilative or ischaemic cardiomyopathy.20 With regard to this argument we should offer these patients a very safe therapy with an additional PHD testing because the potential benefit might be higher in this group.21,22 On the other side, we have to accept a longer in-hospital stay for PHD testing including higher costs and the risk of a second VF induction with all possible complications of VF itself, shock delivery, and sedation. In this context we should address the problem of possible negative side effects of shock delivery. Some data suggest that shocks (e.g. adequate and inappropriate shocks) may be associated with a decreased survival.23 Furthermore, juridical aspects regarding recommendations by the manufacturers should be attended. Some manufacturers require an ICD testing in their manuals and this, in a lot of countries, is a part of the local medical device approvals. This may indicate that other methods are only possible in the context of clinical studies.

Based on the data of this study, the common practice to discharge patients without testing at the time of implantation or PHD cannot be suggested for the whole patient population. In total, 2.1% of all patients (n = 809) with no contraindication for ICD testing had either an ineffective intra-operative test (n = 7, 0.7%) or ineffective PHD (n = 11, 1.4%). Concerning patients without risk factors for PHD failure, a single intra-operative ICD testing at least might be safe and guarantees a sufficient appropriate ICD function. This should be confirmed in further randomized studies; SIMPLE and NORDIC ICD.24,25

However, the conditions for a controlled intra-operative DFT testing and PHD with, e.g. controlled haemodynamics, preoxygenic
Table 3  Patient characteristics with pre-hospital discharge failure, underlying mechanism and solutions

<table>
<thead>
<tr>
<th>#</th>
<th>Age at time of implantation (years)</th>
<th>Body mass index (kg/m²)</th>
<th>Sex m/f</th>
<th>Indication for ICD</th>
<th>LV EF (%)</th>
<th>LVEDD (mm)</th>
<th>High-voltage impedance (Ω)</th>
<th>Effective intra-operative energy (J)</th>
<th>PHD Ineffective energy (J)/sensing failure</th>
<th>Solution of failed PHD</th>
<th>Threshold/sensing of RV lead (V/1ms) (mV)</th>
<th>Device/lead (coil design)/lead position</th>
<th>Antiarrhythmic therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>45.2</td>
<td>20.5</td>
<td>m</td>
<td>DCM</td>
<td>25</td>
<td>64</td>
<td>40</td>
<td>21</td>
<td>21 reversed effective (2 times)</td>
<td>0.8/0.4</td>
<td>18.3</td>
<td>Boston: Vitality 1870 VR/Endotak Reliance EZ 158 (dc)/apical</td>
<td>BB</td>
</tr>
<tr>
<td>2</td>
<td>67.6</td>
<td>24.7</td>
<td>m</td>
<td>ICM</td>
<td>10</td>
<td>68</td>
<td>44</td>
<td>31</td>
<td>41 Sub Q array</td>
<td>0.8/0.4</td>
<td>9.4</td>
<td>Boston: Renewal 4 RF 235/Endotak Reliance EZ 158 (dc)/apical</td>
<td>BB, amiodarone</td>
</tr>
<tr>
<td>3</td>
<td>42.5</td>
<td>25.2</td>
<td>m</td>
<td>ICM</td>
<td>15</td>
<td>68</td>
<td>45</td>
<td>21</td>
<td>20/30 Sub Q array</td>
<td>0.5/0.5</td>
<td>14.8</td>
<td>Biotronik: Lexos VR-T/ Kento SL (dc)/apical</td>
<td>BB</td>
</tr>
<tr>
<td>4</td>
<td>79.9</td>
<td>26.0</td>
<td>m</td>
<td>ICM</td>
<td>35</td>
<td>56</td>
<td>33</td>
<td>17</td>
<td>Sensing failure RV lead revision</td>
<td>0.9/0.4</td>
<td>12.0</td>
<td>Biotronik Belos VR/ Kainox SL 75 (dc)/apical</td>
<td>BB</td>
</tr>
<tr>
<td>5</td>
<td>48.0</td>
<td>30.1</td>
<td>m</td>
<td>DCM</td>
<td>20</td>
<td>72</td>
<td>26</td>
<td>20</td>
<td>20/30 Floating shock coil</td>
<td>1.7/0.5</td>
<td>10.0</td>
<td>Biotronik: Dekos + ICD VDD/Kainox VDD (sc)/apical</td>
<td>BB</td>
</tr>
<tr>
<td>6</td>
<td>63.4</td>
<td>23.6</td>
<td>m</td>
<td>ICM</td>
<td>20</td>
<td>72</td>
<td>48</td>
<td>21</td>
<td>21/31/41 Sub Q array</td>
<td>0.8 V/0.5 ms no iR ¹</td>
<td></td>
<td>Boston Renewal 4/ Endotak Reliance 185 (dc)/apical</td>
<td>BB</td>
</tr>
<tr>
<td>7</td>
<td>52.8</td>
<td>24.0</td>
<td>m</td>
<td>DCM, aortic valve replacement</td>
<td>20</td>
<td>75</td>
<td>38</td>
<td>21</td>
<td>21 reversed effective (2 times)</td>
<td>0.4/0.4</td>
<td>23</td>
<td>Boston Renewal 4/ Endotak EZ 165 (dc)/RV basal</td>
<td>BB, amiodarone</td>
</tr>
<tr>
<td>8</td>
<td>36.5</td>
<td>30.8</td>
<td>m</td>
<td>LQT</td>
<td>40</td>
<td>39</td>
<td>38</td>
<td>21</td>
<td>21 reversed effective (2 times)</td>
<td>0.6 V/0.5 ms 19.1</td>
<td></td>
<td>Boston Vitality 2 VR EL/Endotak Reliance 185 (dc)/apical</td>
<td>BB</td>
</tr>
<tr>
<td>9</td>
<td>39.1</td>
<td>27.1</td>
<td>m</td>
<td>ICM</td>
<td>45</td>
<td>65</td>
<td>38</td>
<td>20</td>
<td>20/31 Sub Q array</td>
<td>1.8 V/0.5 ms 11.6</td>
<td></td>
<td>Medtronic Gem II DR/ 6942 (dc)/apical</td>
<td>BB, amiodarone</td>
</tr>
<tr>
<td>10</td>
<td>25.7</td>
<td>27.7</td>
<td>m</td>
<td>non-Compaction CMP</td>
<td>30</td>
<td>80</td>
<td>41</td>
<td>21</td>
<td>21/31/41 Sub Q array</td>
<td>0.8 V/0.5 ms 13.9</td>
<td></td>
<td>Boston Renewal 4 RF 235/Endotak Reliance 185 (dc)/apical</td>
<td>BB</td>
</tr>
<tr>
<td>11</td>
<td>67.5</td>
<td>26.5</td>
<td>m</td>
<td>DCM</td>
<td>20</td>
<td>82</td>
<td>57</td>
<td>34</td>
<td>Sensing failure P/S lead added</td>
<td>0.3 V/0.5 ms no iR ²</td>
<td></td>
<td>Medtronic Insync Marquis 7289/6932 (dc)/apical</td>
<td>amiodarone</td>
</tr>
</tbody>
</table>

¹IR, intrinsic rhythm; sc, single coil; dc, dual coil; BB, beta blockers.
ICM, ischaemic cardiomyopathy; DCM, dilated cardiomyopathy.
treatment, sedation, and monitoring, differs a lot from the situation of sudden unexpected tachyarrhythmia (syncope, hypoxia, acidosis, ischaemia, and/or shock). \(^\text{26}\) Furthermore, the artificially induced tachyarrhythmia may not represent the spontaneous rhythm disorder in many of the cases, e.g. monomorphic VT in ischaemic cardiomyopathy or bundle branch re-entry in dilative cardiomyopathy. \(^\text{27,28}\) Therefore, a second DFT-test (PHD) under mild sedation potentially gives more information about the real-life situation of VF and its termination.

According to this important fact, the value of a second DFT testing (PHD) is discussed controversially. Gold et al. \(^\text{22}\) have accurately named this controversy: Defibrillation testing at ICD implantation: are we asking the wrong question? Nearly 30% of ICD patients succumb to SCD despite the best therapy we can provide today. \(^\text{29}\) These patients die primarily from VT/VF storm, asystole, pulseless electrical activity, and failure to defibrillate may be based on the progress of heart failure. \(^\text{23}\) These problems are still unsolved due to the fact that ICD therapy is limited to electrical interventions such as antidysrhythmic/antitachydycardic pacing and shock delivery. Electro-mechanical resuscitation devices based on medium-voltage therapy principle are promising to solve this dilemma. \(^\text{30}\) In the meantime, it is a challenging abandonment for physicians and the industry to improve safety of the existing ICD systems and the operational sequences during ICD implantation.

With the implementation of high-energy devices and adaptive entrance sensing filters, two studies were launched to evaluate ICD therapy without any testing in malignant tachyarrhythmia situation (no intra-operative DFT testing, no PHD, no sensing tests in VF). \(^\text{24,25}\) If these new studies confirm a safe endpoint, an ICD implantation will be as easy as a pacemaker implantation. At this time, the results of these studies can only speculate relating to the patients with standard ICD indication. A valid prediction with an adequate statistical power for the minority of ICD indication will be a key point of these studies in the background of the long lifetime of ICD therapy.

However, so far we recommend testing the proper ICD function at least once, and considering certain patients’ characteristics a PHD testing is advisable.

**Study limitations**

The present study was retrospective in design and monocentric. The data include a period of 11 years with different teams for implantation and ICD testing. Therefore, all data of this analysis were evaluated by two independent cardiologists experienced in pacemaker and ICD implantation to improve the quality data base. Nevertheless, there remains a variety of intra-operative practice, different generation of ICD/lead designs, and a not-specific protocol for the DFT testing. Especially, the non-uniform method of DFT testing with marginal differences in the safety-margin method can lead to a problematic outcome analysis with a bias.

Another limitation is the lack of standard protocol for the observation post-hospitalization. Therefore, in this study no follow-up data were included, and thus it cannot quantify possible long-time complications associated with the ICD testing.

**Conflict of interest:** none declared.

**References**


