The quick-implantable-defibrillator trial

Dietmar Bänsch1*, Hans Kottkamp2, Gerian Grönefeld3, Jürgen Vogt4, Carsten Israel3, Dirk Böcker5, Gerd Hindricks2, and Karl-Heinz Kuck1 on behalf of the Quick-ICD investigators

1 Department of Cardiology, St. Georg’s Hospital, Hamburg, Germany; 2 Heart Centre, University Clinic, Leipzig, Germany; 3 Department of Cardiology, J-W-Goethe University, Frankfurt, Germany; 4 Herz- und Diabeteszentrum NRW, Bad Oeynhausen, Germany; and 5 Department of Cardiology and Angiology, Westfaelische Wilhelms-University, Muenster, Germany

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Aims Earlier ICD therapy included an electrophysiological study (EPS), an extensive defibrillation threshold test (DFT), and a pre-discharge test. Now that ICD-therapy is widely accepted, an EPS is no longer performed in most patients, extensive DFT-tests have been reduced to a minimum of two effective shocks and discharge tests have been discarded in most centres. However, it has never been demonstrated prospectively that this simplification is safe.

Methods and results The Quick-Implantable-Defibrillator (Quick-ICD) Trial was a prospective multi-centre trial, which randomized patients, who had survived a cardiac arrest (SCD) or an unstable ventricular tachycardia (VT), to two different clinical strategies: (a) The extensive strategy included an EPS, an extensive DFT-test, and a pre-discharge test; (b) In the simplified approach (quick strategy) the ICD was implanted without an EPS and a pre-discharge test. Two effective shocks during implantation at 21 J were sufficient. The primary endpoint of this trial was a cluster of adverse events related to the diagnostic approach and to ICD-therapy. One hundred and ninety patients were included, 97 randomized to the extensive-, 93 to the quick strategy. Mean follow-up was 12 ± 7 months. Twenty-seven patients reached the endpoint in the quick group and 32 in the extensive group. During follow-up, the event-free survival was equal in the two study arms (test for equivalence, \( P = 0.0044 \)). The initial hospital stay was significantly shorter in the quick population (8.4 ± 4.7 vs. 11.2 ± 7.4 days, \( P = 0.004 \)).

Conclusion It is safe and cost-effective to implant an ICD without an EPS, an extensive DFT-, and a pre-discharge test in carefully selected patients after survived SCD or unstable VTs.

KEYWORDS Implantable cardioverter defibrillator; Programmed ventricular stimulation; Defibrillation threshold testing; DFT; ICD

Introduction The implantation of a cardioverter-defibrillator (ICD) has become the therapy of choice for secondary and primary prevention of sudden cardiac death.1

In the majority of patients, an electrophysiological study (EPS) has been recommended before ICD-implantation for various reasons: first, to exclude a curable cause of the cardiac arrest (CA), such as a supraventricular tachycardia (SVT), a WPW-syndrome, a bundle branch re-entry tachycardia or an idiopathic VT and to determine AV-nodal conduction properties.2–4 Secondly, programmed ventricular stimulation (PVS) has been performed for risk stratification in patients with reduced LV-function and non-sustained VTs.5,6 Thirdly, patients with stable VTs may be candidates for antiarrhythmic drug therapy or radiofrequency ablation.7–9 Finally, inducible VTs and AV-nodal conduction properties have influenced the programming of the ICD, i.e. the tachycardia detection rate and enhancement criteria in patients, in whom a documentation of VTs is often lacking due to the potential deterioration of VTs into VF.2,4,10,11

Furthermore, most patients underwent a systematic extensive defibrillation threshold (DFT) test, in order to verify VF-detection and adjust first shock energy.12 Defibrillation tests have been repeated before discharge to test reproducibility of the extensive DFT.13

Now that ICD therapy is widely accepted to be safe, the approach to ICD therapy has been simplified: an EPS is felt unnecessary if no curable cause for a survived cardiac arrest is suspected, extensive DFT-tests have been reduced to a minimum of two effective shocks and a pre-discharge test is discarded altogether in most centres. However, it has never been demonstrated prospectively that such a simplification is safe and justified. Therefore, the purpose of this randomized multi-centre study was to compare a simplified approach to ICD-therapy without EPS, extensive DFT-, and pre-discharge-tests (quick strategy) with an extensive approach including these tests.

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Methods

Hypothesis

The outcome of patients without EPS, extensive DFT-, and preshock test (quick group) is not inferior to the outcome of patients with an extensive approach to ICD-implantation including these tests.

Patients

Patients between the age of 18 and 80 years with structural heart disease [coronary artery disease (CAD), idiopathic dilated cardiomyopathy (DCM), valvular heart disease, arrhythmogenic right ventricular cardiomyopathy] were included in this trial, if they had survived a CA or an unstable VT, requiring cardioversion or defibrillation during resuscitation, i.e., patients with a Class I indication for an ICD-implantation.1

Patients with congestive heart failure NYHA IV at the time of randomization, a life expectancy of <1 year or contra-indications for extensive testing were not eligible for this study. Patients were also excluded, if secondary causes for CA were likely (ischemia or infarction at the time of CA, pre-excitation, AV-time <0.12 s, QTc-interval >0.55 s, Brugada syndrome) or if the CA was due to a sick sinus node or AV-block II or III. Patients without a structural heart disease, normal LV-function (EF >55%) or only LV-hypertrophy (>14 mm) were excluded, since the likelihood of a curable cause of the SCD was supposed to be too high in these patients.2,4

Endpoints

The primary endpoint was a combined endpoint of typical adverse events in ICD-patients, including death, complications (due to diagnostic procedures or ICD therapy), under-detected VTs (VTs below the detection rate or with a therapy delay >2 min due to enhancement criteria), syncope, inappropriate therapies, clusters of shocks, and ineffective first shocks. It was expected that the EPS and DFT testing in the extensive arm would improve VT detection, differentiation, and termination of VT and thereby reduce the risk of 5 under-detected VTs, syncope, inappropriate therapies, VT clusters, and ineffective shocks.

Secondary endpoints were those therapeutic decisions taken before, during, or after ICD-implantation, which were influenced by the EPS, extensive DFT-, or preshock tests, such as the decision to withhold ICD-therapy based on findings in the EPS, the decision for RF-ablation, the selection of a dual chamber ICD or the programming of a lower detection rate based on inducible slow VTs during PVS, the programming of enhancement criteria, the reduction of the first shock energy or the implantation of an array electrode based on findings during the extensive DFT tests.

As a secondary endpoint and a surrogate for health care utilisation, the number of invasive procedures, days of primary hospitalization, out-patient visits, and days in hospital during follow-up were documented.

Procedure

The study was approved by the FEKI (registered Ethical Board in Freiburg, Germany) and the Ethical Board of each institution, which took part in the study. Patients, who met the inclusion criteria, were randomized centrally after a written informed consent was obtained. All patients received a baseline ECG, a holter-ECG, a transthoracic echocardiogram, and a coronary and left ventricular angiography before randomization.

Patients randomized to the extensive approach underwent an EPS, to exclude an accessory pathway, determine antegrade and retrograde Wenckebach periodicity, and the effective atrial refractory period. In addition, a PVS was performed at two baseline cycle lengths (500 and 400 ms) with up to three extra-stimuli in RV apex and RV outflow tract until a VT was induced or the ventricular refractory time was reached. During ICD-implantation, an R-wave sensing of at least 9 mV and a pacing threshold of $<1.5 V$ at 0.5 ms was aimed at. The extensive defibrillation threshold (DFT+) was determined according to a step-down step-up protocol presented elsewhere,12 during which the last effective shock had to be repeated in order to qualify for a DFT+. We started with a shock-energy of 12 J, if effective we went down by steps of 3 J and up again by 3 J. If the first shock energy of 12 J was ineffective, the next step was 18 J and then down by 3 J. If 18 J were ineffective 24 J were tried, if ineffective electrode revision was recommended and if 24 J were still ineffective an array electrode was recommended in the protocol. If all these approaches were still ineffective, a high-energy device was implanted. Before discharge the DFT was re-evaluated. If it was reproducible, the first shock energy was programmed to the extensive DFT + 10 J. The detection rate was programmed according to the slowest spontaneous or inducible VTs with a safety margin of 30–60 ms. The programming of additional detection criteria, such as cycle length stability and acceleration was left to the discretion of the implanting physician.

In the quick strategy, the ICD was implanted directly after randomization. The implantation requirements were the same as in the extensive arm, except that only two effective shocks at 21 J were sufficient. The first shock energy was programmed to the maximum. The VT-detection rate was programmed at 170–180 bpm and the VF detection at 200–220 bpm, if no VT was documented. In these patients no pre-discharge test was performed.

Statistical consideration

The study was designed as a non-inferiority study with a comparison of cumulative rates of events in the two groups (quick vs. extensive) after 18 months. On the basis of the literature, the cumulative event rate for the combined primary endpoint was expected to be 0.68 after 18 months (10, 14–17). With a recruitment time of 1 year, a duration of the study of 3 years, an estimated loss-of-follow-up of 2% per year, an alpha of 0.025 (one-sided) and a power of 0.8, the necessary number of patients to demonstrate non-inferiority of 14% was calculated to be $n = 286$. Calculations were performed using the logrank test model of Lachin and Foulkes within the framework of Nsurv program from idv. (18–20) After 2 years, a blind sample size re-assessment was made, because the cumulative event rate (pooled groups) was only 30% and enrolment of more patients became difficult. Based on $P = 0.3, n = 190$, and a study duration of 2 years, the new calculation showed that the obtainable boundary for inferiority was about 20%.

Study organization and conduct

The study was supported by Guidant GmbH, Germany. Seventeen German centres participated in study. Randomization was performed centrally by fax. The database was also located at the sponsor’s headquarter. The statistical endpoint analysis was performed by two independent statisticians: Andreas Rozehnal, MD, and Volker W. Rahls, senior biometrician, IDV Datenanalyse und Versuchsplanung, Gauting, Germany.

Results

Patients

Patient’s baseline characteristics are presented in Table 1. One hundred and ninety-six patients were included in the trial. Data of 190 patients could be analysed, 93 in the quick and 97 in the extensive group. For six patients only randomization but no follow-up data were available.

Despite randomization, the two groups revealed some differences concerning heart disease, infarction, and the presence of atrial fibrillation (Table 1). More patients had a CAD and a history of an inferior myocardial infarction in
shock energy was programmed to a mean of 23 tation strategy in only 3 of 190 patients (1.6%). Therefore, all defibrillation tests led to a change in implan-
da high-energy device nor an array electrode was implanted. defibrillation with 21 J. In the extensive population, neither one patient received a high-energy device due to insufficient detection rate. All other dual chamber ICDs were implanted due to pacemaker indications. The DFT was 12 ± 6 J in the extensive group. In whom a high voltage device was used with a shock energy of 40 J.

Baseline electrophysiological study

All patients in the extensive group underwent an EPS. An accessory pathway was excluded in all patients. 51.6% of the patients had an inducible VT. None exhibited an idio-
pathic or a bundle branch re-entry tachycardia. The cycle length of the slowest induced VTs was 288 ± 53 ms. One patient underwent RF- ablation of a VT and two of inducible supraventricular tachycardias (atrial flutter, AVNRT). Nine patients had an inducible VT below 180 bpm, which had not previously been documented. The decision to implant an ICD was not revised in any of the extensive patients. Four of the quick patients underwent an EPS before the implantation because of frequent VTs with the intention to ablate these VTs. All of them had inducible VTs, two finally underwent VT ablation, two received an antiarrhythmic drug therapy with amiodarone.

ICD-implantation and programming

All ICD implantations were successful at the first attempt. Five patients (5.2%) received a dual chamber ICD in the extensive and three (3.2%) in the quick population. In the extensive group, two patients received a dual chamber ICD on the assumption that a dual chamber detection algorithm may prevent inappropriate therapies in patients with a low detection rate. All other dual chamber ICDs were implanted due to pacemaker indications.

In the quick arm two patients received an array electrode, one patient received a high-energy device due to insufficient defibrillation with 21 J. In the extensive population, neither a high-energy device nor an array electrode was implanted. Therefore, all defibrillation tests led to a change in implantation strategy in only 3 of 190 patients (1.6%).

The DFT was 12 ± 6 J in the extensive group. The first shock energy was programmed to a mean of 23 ± 6 J, i.e. a reduction to below or equal 21 J was possible in 32 patients (Table 2), because the DFT was reproducible in all patients during pre-discharge tests. The mean detection rate was similar in both groups (173 ± 7 vs. 174 ± 11 bpm, P = 0.62), but there were more patients with a detection rate below 170 bpm in the extensive group (n = 11 vs. 5, P = 0.19).

Additional detection criteria were more often programmed ‘on’ in the quick group. The stability criterion was programmed ‘on’ in 81.0 and 67.0% of patients in the quick and extensive population, respectively (P = 0.04). The onset criterion was programmed ‘on’ in 80.6 and 71.1% of patients in the quick and the extensive population, respectively (P = 0.15).

Primary endpoint

Twenty-seven patients reached the combined endpoint in the quick population (29%) as opposed to 32 patients in the extensive population (33%, Table 2). After 18 months, 66.8% of the patients survived free of an endpoint in the quick limb and 62.7% in the extensive limb, respectively (Figure 1). Assuming an inferiority margin of 20%, the test for non-inferiority resulted in P = 0.0044. With an alpha error of P = 0.025 (one-sided test), non-inferiority could be statistically proved up to a bound of 13.8%. For the primary endpoint excluding death, similar results could be obtained: the test for equivalence resulted in a P = 0.0036.

The trial was not large enough to provide sufficient power for the subgroups and sub-endpoints. With respect to the statistical problem of multiple and post-hoc tests, these

### Table 1 Patients baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Quick</th>
<th>Extensive</th>
<th>P-value</th>
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</thead>
<tbody>
<tr>
<td>n</td>
<td>93</td>
<td>97</td>
<td></td>
</tr>
<tr>
<td>Age, yrs</td>
<td>64 ± 10</td>
<td>62 ± 12</td>
<td>0.38</td>
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<tr>
<td>Male, %</td>
<td>89.3</td>
<td>82.5</td>
<td>0.23</td>
</tr>
<tr>
<td>CAD, %</td>
<td>57.0</td>
<td>70.1</td>
<td>0.08</td>
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<tr>
<td>DCM, %</td>
<td>30.1</td>
<td>22.7</td>
<td>0.23</td>
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<tr>
<td>Valvular disease, %</td>
<td>6.5</td>
<td>4.1</td>
<td>0.46</td>
</tr>
<tr>
<td>Other, %</td>
<td>6.4</td>
<td>3.1</td>
<td>0.53</td>
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</table>

<table>
<thead>
<tr>
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<th>Quick</th>
<th>Extensive</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Infarction, %</td>
<td></td>
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<td></td>
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<tr>
<td>Anterior</td>
<td>20.4</td>
<td>22.7</td>
<td>0.75</td>
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<tr>
<td>Inferior</td>
<td>11.8</td>
<td>22.7</td>
<td>0.052</td>
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<td>Functional classification</td>
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<tr>
<td>NYHA I, %</td>
<td>18.3</td>
<td>20.6</td>
<td></td>
</tr>
<tr>
<td>NYHA II, %</td>
<td>53.8</td>
<td>52.6</td>
<td>0.75</td>
</tr>
<tr>
<td>NYHA III, %</td>
<td>21.5</td>
<td>21.6</td>
<td></td>
</tr>
<tr>
<td>Not documented, %</td>
<td>6.4</td>
<td>5.2</td>
<td></td>
</tr>
<tr>
<td>Ejection fraction, %</td>
<td>40 ± 17</td>
<td>41 ± 16</td>
<td>0.55</td>
</tr>
<tr>
<td>Atrial fibrillation, %</td>
<td>34.4</td>
<td>26.8</td>
<td>0.25</td>
</tr>
<tr>
<td>PQ-duration, ms</td>
<td>177 ± 31</td>
<td>176 ± 30</td>
<td>0.83</td>
</tr>
<tr>
<td>QRS-duration, ms</td>
<td>110 ± 29</td>
<td>114 ± 30</td>
<td>0.44</td>
</tr>
<tr>
<td>QT-duration, ms</td>
<td>410 ± 42</td>
<td>407 ± 48</td>
<td>0.91</td>
</tr>
</tbody>
</table>

*The first shock was always programmed to 30 J except for one patient

### Table 2 Patients presenting arrhythmias, results of EPS, DFT-tests, and ICD-programming

<table>
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<tr>
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<th>Quick</th>
<th>Extensive</th>
<th>P-value</th>
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<tbody>
<tr>
<td>n</td>
<td>93</td>
<td>97</td>
<td></td>
</tr>
<tr>
<td>Presenting arrhythmia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survived SCD</td>
<td>83.9</td>
<td>88.7</td>
<td>0.37</td>
</tr>
<tr>
<td>Defibrillation, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fast VT, %</td>
<td>19.4</td>
<td>14.4</td>
<td></td>
</tr>
<tr>
<td>VT (documented), %</td>
<td>44.1</td>
<td>40.2</td>
<td>0.60</td>
</tr>
<tr>
<td>VT CL, ms</td>
<td>267 ± 51</td>
<td>271 ± 32</td>
<td>0.71</td>
</tr>
<tr>
<td>Baseline EPS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>4</td>
<td>97</td>
<td></td>
</tr>
<tr>
<td>Inducible VT/VF (n), %</td>
<td>100</td>
<td>51.6</td>
<td></td>
</tr>
<tr>
<td>VT CL slowest, ms</td>
<td>326 ± 159</td>
<td>288 ± 53</td>
<td></td>
</tr>
<tr>
<td>VT CL fastest, ms</td>
<td>280 ± 104</td>
<td>267 ± 32</td>
<td></td>
</tr>
<tr>
<td>VT CL mean, ms</td>
<td></td>
<td>271 ± 59</td>
<td></td>
</tr>
<tr>
<td>VT &gt; 330 ms (n), %</td>
<td>50</td>
<td>9.2</td>
<td></td>
</tr>
<tr>
<td>VT Inducible</td>
<td>-</td>
<td>9.3</td>
<td></td>
</tr>
<tr>
<td>(Afib/Aflur/AVNRT)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>DFT</td>
<td>17 ± 4 J</td>
<td>12 ± 6 J</td>
<td>&lt;0.01</td>
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</tbody>
</table>

ICD-programming

<table>
<thead>
<tr>
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<th>Quick</th>
<th>Extensive</th>
<th>P-value</th>
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</thead>
<tbody>
<tr>
<td>VF zone (bpm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>208 ± 10</td>
<td>209 ± 10</td>
<td>0.43</td>
<td></td>
</tr>
<tr>
<td>VT zone (bpm)</td>
<td>173 ± 7</td>
<td>174 ± 11</td>
<td>0.62</td>
</tr>
<tr>
<td>VT zone &lt; 170 bpm (n), %</td>
<td>5.4</td>
<td>11.3</td>
<td>0.19</td>
</tr>
<tr>
<td>Shock-energy</td>
<td>30§</td>
<td>23 ± 6</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Stability ‘on’, %</td>
<td>81.0</td>
<td>67.0</td>
<td>0.04</td>
</tr>
<tr>
<td>Onset ‘on’, %</td>
<td>80.6</td>
<td>71.1</td>
<td>0.15</td>
</tr>
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</table>

*The first shock was always programmed to 30 J except for one patient

In whom a high voltage device was used with a shock energy of 40 J.
data are only provided in a descriptive sense without tests of significance. The effect of both strategies was similar in the following subgroups: gender, heart disease, sinus-rhythm, atrial fibrillation, presenting arrhythmia, detection rate, and first shock energy (Figure 2). There was a tendency for younger patients to profit from the quick approach as opposed to older patients (>70 years of age): odds ratio 0.67 (0.36–1.24) vs. 1.70 (0.62–4.76). The same was true for patients in NYHA III: odds ratio 0.32 (0.09–1.10) vs. 1.33 (0.50–3.57, Figure 2).

Nine patients died in the quick group and seven in the extensive group. Two deaths were sudden in each group, one cardiac in the quick and two in the extensive group. Three deaths remained undefined in the quick study arm, two in the extensive arm. After 18 months, 88.3 and 91.0% of the patients were still alive in the quick and the extensive group, respectively. Inferiority of the quick strategy could obviously not be excluded (P = 0.31), due to small patient numbers and few events. Complications occurred in four patients in the quick population, due to ICD-therapy in three (haematoma, perforation, lead dislodgements) and due to RF-ablation of a VT in one. Two of these complications were fatal. The patient after VT ablation died within 48 h of the procedure, the reason for which did not become clear since post-mortem examination was denied by the relatives. The patient with perforation died, since pericardial effusion occurred slowly and lead to haemodynamic compromise after dismissal from the hospital.

Ventricular tachycardia-associated syncope occurred more often in the extensively studied population. After 18 months, 94.7% of the quick patients survived free of syncope as opposed to 87.9% of the patients in the extensive group. Ineffective first shocks occurred in five quick patients (5.4%) and in seven patients (7.2%) in the extensive group with a reduction of the first shock energy according to the results of the extensive DFT test.

Inappropriate therapies were frequent in both populations despite a fairly high detection rate and the use of additional detection criteria in 67.0–81.0% of patients. Ten of 93 patients suffered inappropriate therapies in the quick and 14 of 97 patients in the extensive population (P = 0.52). Ventricular tachycardias below the detection rate or with a detection delay of more than 2 min occurred in five patients in each study group despite a reduction of the detection rate according to the results of the PVS in nine of the extensive group. Shock clusters (>2 shocks/day) were not different between the groups (Table 3).

Economic assessment

There was no difference in ambulatory visits (quick: median 10, 95% CI 7–13 vs. extensive: median 10, 95% CI 8–12) or days in hospital for any reason including rehabilitation (quick: median 29, CI 20–38 vs. extensive: median 28, CI 22–35) during follow-up. However, the number of invasive procedures was significantly lower in the quick population (median 2, CI 1.5–2.5 vs. median 3, CI 2.4–3.7, P = 0.002) and therefore the initial hospital stay was significantly shorter (8.4 ± 4.7 vs. 11.2 ± 7.4 days, P = 0.004).

Discussion

Primary endpoint

The Quick-ICD-trial is the first study to demonstrate prospectively that selected patients with a Class I ICD-indication for secondary prevention of SCD or unstable VTs do not have any disadvantage if they are implanted without an EPS, an extensive DFT-, or a predischarge test, provided that secondary causes of sudden cardiac death are unlikely and the diagnosis of VT/VF is certain on clinical grounds. The primary endpoint of this trial was a combined endpoint including all-cause mortality, complications, syncope, clusters of shocks, inadequate therapies, VTs with a significant detection delay or below the detection rate, and ineffective first shocks. The survival free of the primary endpoint was equal in the quick and extensive group (P = 0.0044). This was supported by the comparison of odds ratios and lower confidence intervals in both groups. Younger patients in good functional status even seemed to profit from the quick strategy compared to older patients and patient in functional Class III.

Mortality was low in both groups, ranging between 7.2 and 9.7% per year in the extensive and quick population, respectively. Non-inferiority of the quick strategy was not planned to be and could not be demonstrated for this endpoint due to small number of patients and events. This might indicate a disadvantage of the quick strategy. However, a trial to demonstrate non-inferiority for mortality would require at least a couple of thousand patients.
The risk of an endpoint or death at 18 months was expected to be more than 70% based on available literature at the time when the trial was designed. However, 68–72% of patients survived free of an endpoint at 18 months. Therefore, ICD therapy nowadays is safe and associated with fewer complications and adverse events during follow-up than reported previously (10, 14–17).

Inappropriate therapies are still the most frequent adverse events in ICD-patients. Between 10 and 14% of patients suffered inappropriate therapies although the mean detection rate was high (174 bpm) and additional detection criteria were programmed ‘on’ in 67.0–81.0% of patients. Interestingly, the results of the EPS seemed to have falsely suggested that additional detection criteria might not be necessary in some patients. Instead, enhancement criteria should be programmed ‘on’ in all patients with a VT zone below 200 bpm, because the risk of inappropriate therapies increases with a lower detection rate and a progressive overlap between VT and SVT cycle lengths (21,22).

Ventricular tachycardias below the detection rate or with detection delay were not different between the groups, although the detection rate was reduced considerably in nine patients due to slow inducible VTs (180 bpm) in the extensive group. Programming the detection rate according to inducible VTs may not have a significant impact on follow-up. Previous reports suggest that a significant slowing of VTs during follow-up seems to be rather determined by additional antiarrhythmic drug therapy and heart failure than by inducible VTs at baseline.10

Clusters of shocks were not different between the two groups. It could have been expected that the VT-zone would have been programmed more appropriately or

Table 3: Decisions and events

<table>
<thead>
<tr>
<th>Decision</th>
<th>Quick</th>
<th>Extensive</th>
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<tbody>
<tr>
<td>n</td>
<td>93</td>
<td>97</td>
</tr>
<tr>
<td>Follow-up (months)</td>
<td>12 ± 7</td>
<td>12 ± 8</td>
</tr>
<tr>
<td>Special decisions, %</td>
<td>7.5</td>
<td>8.3</td>
</tr>
<tr>
<td>ICD therapy withheld, %</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>DDD-ICD, %</td>
<td>3.2</td>
<td>5.2</td>
</tr>
<tr>
<td>RF Ablation (VT/SVT), %</td>
<td>2.1</td>
<td>3.1</td>
</tr>
<tr>
<td>Array, %</td>
<td>2.2</td>
<td>0</td>
</tr>
<tr>
<td>high-energy device, %</td>
<td>1.1</td>
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<tr>
<td>Endpoint events</td>
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<tr>
<td>Complication, %</td>
<td>4.3</td>
<td>1.0</td>
</tr>
<tr>
<td>Shock cluster, %</td>
<td>4.3</td>
<td>3.1</td>
</tr>
<tr>
<td>Syncope, %</td>
<td>3.2</td>
<td>13.4</td>
</tr>
<tr>
<td>Inappropriate therapy, %</td>
<td>10.8</td>
<td>14.4</td>
</tr>
<tr>
<td>VT not detected, %</td>
<td>5.4</td>
<td>5.2</td>
</tr>
<tr>
<td>First shock ineffective, %</td>
<td>5.4</td>
<td>7.2</td>
</tr>
<tr>
<td>Death, %</td>
<td>9.7</td>
<td>7.2</td>
</tr>
<tr>
<td>Sudden/non-sudden/unknown (n)</td>
<td>(2/4/3)</td>
<td>(2/3/2)</td>
</tr>
<tr>
<td>Cardiac/non-cardiac/unknown (n)</td>
<td>(1/5/3)</td>
<td>(2/3/2)</td>
</tr>
<tr>
<td>Patients with endpoint (n)</td>
<td>27</td>
<td>32</td>
</tr>
</tbody>
</table>

Data are presented in a descriptive sense without tests due to the problem of multiple testing and because the study was not powered for the sub-endpoints.

The risk of an endpoint or death at 18 months was expected to be more than 70% based on available literature at the time when the trial was designed. However, 68–72% of patients survived free of an endpoint at 18 months. Therefore, ICD therapy nowadays is safe and associated with fewer complications and adverse events during follow-up than reported previously (10, 14–17).

Inappropriate therapies are still the most frequent adverse events in ICD-patients. Between 10 and 14% of patients suffered inappropriate therapies although the mean detection rate was high (174 bpm) and additional detection criteria were programmed ‘on’ in 67.0–81.0% of patients. Interestingly, the results of the EPS seemed to have falsely suggested that additional detection criteria might not be necessary in some patients. Instead, enhancement criteria should be programmed ‘on’ in all patients with a VT zone below 200 bpm, because the risk of inappropriate therapies increases with a lower detection rate and a progressive overlap between VT and SVT cycle lengths (21,22).

Ventricular tachycardias below the detection rate or with detection delay were not different between the groups, although the detection rate was reduced considerably in nine patients due to slow inducible VTs (<180 bpm) in the extensive group. Programming the detection rate according to inducible VTs may not have a significant impact on follow-up. Previous reports suggest that a significant slowing of VTs during follow-up seems to be rather determined by additional antiarrhythmic drug therapy and heart failure than by inducible VTs at baseline (10).

Clusters of shocks were not different between the two groups. It could have been expected that the VT-zone would have been programmed more appropriately or
patients with inducible VTs would undergo RF-ablation as an adjunct to ICD-therapy. However, VT ablation was only performed in three patients. The decision to ablate a VT was rather based on clinical criteria than on EPS results.

Syncope occurred more often in the extensive group. This was not due to the reduction of the first shock energy. A comparison between patients with reduced first shocks and maximum first shock revealed that a reduction of first shock energy did not increase the risk of syncope. However, a significant reduction of shock energy was only feasible in patients with a DFT below 21 J. If we had aimed at a low DFT in all patients with the implantation of an array electrode, this strategy might have been more successful. In one study, in which the DFT was determined by upper threshold of vulnerability (ULV) and first shock energy programmed to ULV + 5 J, no syncope occurred during follow up. The ULV + 5 J corresponds to a DFT + 8 J in the Quick-ICD trial. This would strongly favour some kind of DFT test during implantation and programming of first shock energy according to the DFT. However, patients in the Quick-ICD trial did not have any benefit from extensive DFT testing. Interestingly, only 3 of 196 patients (1.6%) received an array (n = 2) or a high-energy device (n = 1). This raises the question whether DFT-tests are still mandatory in all patients with current biphasic devices, if lead position, sensing, and pacing threshold are acceptable.

Secondary endpoints

ICD-implantation was performed in all of the 97 extensively tested patients. No patient was found to have a tractable cause of VF or VT, such as an accessory pathway, an idio-pathic VT, or a bundle branch re-entry tachycardia.

This is in contrast to a study on 290 consecutive patients with aborted sudden cardiac death reported by Wang et al., in which 13 patients (4.5%) had SVTs, which were supposed to have caused the CA. Six of these patients had no heart disease, one coronary spasms, and one patient had a DCM with only slightly depressed LV-function (EF 0.55) and an atrio-fascicular bypass tract with pre-excitation. These patients would have been excluded 13 from the Quick-ICD trial. In one patient, with DCM and an impaired LV-function, VF was supposed to have started from atrial flutter. This patient would have been implanted in the quick strategy, the risk of an error being in the range of 0.35%.

In another retrospective study by Becker on 462 consecutive patients referred to an EPS (223 with the initial diagnosis of VT and 239 with the diagnosis of VF), ICD implantation could be avoided in 14 patients with VF (5.9%) and 44 patients with VT (19.7%) due to results of the EPS.

In three patients, the CA was supposed to be due to atrial flutter with 1:1-conduction (n = 1), atrial fibrillation with WPW-syndrome (n = 1), and AVNRT with fast conduction (n = 1). In 11 patients (4.6%) marked conduction abnormalities were supposed to be the cause of the CA. However, these patients never required defibrillation during resuscitation. All patients with conduction abnormalities and no defibrillation and the patient with WPW-syndrome would have been excluded from the Quick-ICD-trial. The one patient with AVNRT had an EF of 0.30 and would have received an ICD in the Quick-ICD trial. The Quick-ICD strategy would have, possibly falsely, lead to the implantation of an ICD in the patient with atrial flutter and fast conduction, the mistake being in the range of 0.69%.

As far as the patients with VTs were concerned, it is not clear in the study by Becker and Schoels, which criteria were used to diagnose VT in the first place and obviously any admission diagnosis of VT with any cycle length was included in the trial. The only diagnosis, which could have passed unrecognized without an EPS, was one BBR tachycardia in one patient. The obvious mistake in the Quick-ICD trial would therefore be 0.45%. However, BBR tachycardias are infrequently the only VT in patients with a structural heart disease and mainly occur in patients with a dilated cardiomyopathy or a valvular heart disease and an HV-interval of more than 64 ms. A minimal EPS in such patients with determination of HV-interval may be a reasonable compromise.

Economic evaluation

Costs of ICD-therapy could be reduced significantly in patients quickly implanted. The time of initial hospitalization was reduced from 11.2 ± 7.4 to 8.4 ± 4.7 (P < 0.01). The number of outpatient visits and hospitalization during follow-up was not different between the two study groups. This is in line with one study by Wever et al. which demonstrated that EPS-guided therapy did not improve outcome but increased costs as opposed to immediate ICD implantation.

Limitations

The results of this study are statistically well founded. However, the number of patients may be too small to detect rare problems, such as bundle-branch-reentry-tachycardias as a curable cause of a cardiac arrest. Whether these rare problems are sufficient to justify extensive testing in all patients must weight against the procedural risks. Extensive DFT-testing may even be of less importance if high-energy devices are used in the first place.

Besides, the quick approach to ICD implantation in hospitals, which do not have the option of extensive testing or therapy escalation, needs to be viewed with caution. Furthermore, non-inferiority of the quick strategy concerning mortality was not intended and could not be demonstrated due to small numbers of patients and events.

Conclusion

The results of the Quick-ICD trial demonstrated that ICD-implantation without an EPS, an intraoperative extensive DFT-test, and a pre-discharge ICD test is nowadays safe and cost-effective in selected patients after survived CA or an unstable VTs. An uncertainty concerning the decision for or against implanting an ICD may be in the range of about 0.35–0.69%. Patients without any structural heart disease, with a short AV-time or a delta wave and patients with secondary causes of the CA (bradycardia, ischaemia) should still undergo an EPS as needed. Whether a test of defibrillator function during implantation is still necessary in all patients needs further investigation.
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