Comparison of a Novel, Single-Lead Atrial Sensing System With a Dual-Chamber Implantable Cardioverter-Defibrillator System in Patients Without Antibradycardia Pacing Indications
Results of a Randomized Study

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Background—Supraventricular tachyarrhythmias are the main cause for inappropriate therapy by implantable cardioverter-defibrillators (ICDs). For better rhythm discrimination, an atrial electrogram is helpful and usually obtained from an additional atrial lead, even in the absence of sinus node or atrioventricular nodal disease. An A+-ICD system with integrated atrial sensing rings mounted 15 to 18 cm from the tip of an ICD lead may obviate the need to implant a separate atrial lead. The aim of the study was to compare the novel A+-ICD and a conventional dual-chamber (DR)-ICD.

Methods and Results—Two hundred forty-nine patients with standard ICD indications but no requirement for antibradycardia pacing were randomized to receive an A+-ICD (n=124) or a DR-ICD (n=125). Implantation details, need for ICD system revision, long-term sensing, documented arrhythmia episodes, and the respective rhythm discrimination during follow-up were analyzed. The implantation time was significantly shorter in the A+-ICD group (67±30 vs 79±30 minutes, P=0.003). Mean P-wave amplitudes were 3.5±0.8 mV (A+-ICD) and 3.2±0.6 mV (DR-ICD) and remained stable during the follow-up period of 12 months. Surgical revision was necessary in 13 patients in the DR-ICD and 10 in the A+-ICD group. All 593 ventricular tachyarrhythmia episodes were correctly discriminated. Sensitivity and specificity of supraventricular tachyarrhythmia discrimination were not different between the study groups.

Conclusions—The novel A+-ICD system can be implanted faster and is equivalent to a standard DR-ICD with regard to the detection of ventricular tachyarrhythmias and supraventricular tachyarrhythmias. It represents a useful alternative to obtain atrial sensing.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00324662.

Key Words: sudden cardiac death ■ implantable defibrillator ■ tachyarrhythmias

Therapy with implantable cardioverter-defibrillators (ICDs) is established for secondary and primary prevention of sudden cardiac death.1-5 Most patients receive their ICD for primary prevention, but only a minority require antibradycardia pacing. In patients who do not need cardiac resynchronization therapy in combination with ICD treatment, pacing has untoward effects.6 This notwithstanding, many patients without pacing requirements receive an atrial lead to obtain an atrial electrogram (AEGM) for improved atrial rhythm monitoring and for better discrimination of supraventricular tachyarrhythmias (SVTs) and ventricular fibrillation (VF) or ventricular tachycardia (VT). Addition of an atrial lead, however, may increase the risk of complications and may prolong implantation and fluoroscopy times.

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The need to implant a separate atrial lead may be obviated by a novel A+ single-coil defibrillation lead with 2 integrated rings mounted 15 to 18 cm from the lead tip. The rings function as a sensing dipole that floats within the right atrium. In conjunction with a dedicated atrial-input stage that filters
and amplifies the atrial signal up to 4-fold, the A+ -ICD system has been proven safe and operational.7–10 This prospective study aimed to compare the A+ -ICD with the conventional dual-chamber ICD (DR-ICD) concept in a large patient cohort at implantation and during 12 months of follow-up.

Methods

The Belos A+ versus DR Clinical Investigation of Arrhythmia Discrimination (ADRIA) study enrolled 265 patients in 10 centers in Germany and Switzerland (see Appendix). The study protocol was approved by the institutional review boards. The aim of the study was to evaluate potential advantages and disadvantages of an A+ -ICD system in comparison with a conventional DR-ICD. The primary objective of this study was to determine whether there is a difference in the specificity of SVT detection between the 2 systems. Secondary objectives were the comparison of the sensitivities of the detection enhancement algorithm, complication rates, implantation and fluoroscopy times, and lead performance over time.

The study was sponsored by the manufacturer of the devices (Biotronik SE, Berlin, Germany). Before publication the data were reviewed, but the content of the manuscript was not influenced by Biotronik.

Patient Selection

Patients with a standard ICD indication were enrolled in the study.1 Exclusion criteria were the need for antiarrhythmic pacing, permanent atrial fibrillation, life expectancy <6 months, pregnancy, and age <18 years. All patients provided written, informed consent.

Device Specifications

After enrollment, patients were randomized to receive either a standard DR-ICD (Belos DR, Lexos DR, or Lumos DR-T) that required implantation of 2 electrodes or an A+ -ICD (Belos A+ or Lexos A+) with a single A+ lead (Kainox A+ or Kentrox A+). All ICDs and A+ leads were manufactured by Biotronik SE, Berlin, Germany. Other leads could be selected at the discretion of the operator.

The A+ lead combines a single ventricular-shock coil, bipolar sensing and pacing in the right ventricle, and true bipolar sensing in the right atrium with the aid of 2 rings spaced 15 mm apart (Figure 1). The position exactly in the middle between the rings is located 15 or 17 cm from the lead tip. All A+ leads had a passive ventricular fixation mechanism and silicon lead insulation. The older Kainox A+ lead had a significantly larger surface area of the ventricular tip electrode (6.0 mm²) than the successor Kentrex A+ lead (1.8 mm²).

The A+ -ICD systems differ from the DR-ICD systems in 3 aspects: they have no atrial pacing capability, they use a preamplifier for the atrial sensing channel, and they contain only 1 right ventricular-shock coil. The devices were equal with respect to programmability, diagnostic memory characteristics, and the employed tachycardia discrimination algorithm (SMART). The latter classifies all ventricular events as SVTs or VTs, depending on the RR and PP interval, and their respective regularity and multiplicity, as described in the literature.11 When programmable, the QRS detection criteria are met, the episode is stored, including 1 minute of a dual-chamber intracardiac EGM preceding detection. In case of an SVT without coexistent VT or VF, antitachycardia therapy is withheld.

Implantation

Implantations were performed according to institutional standards. The total implantation time, the time between the beginning of lead insertion and lead(s) connection to the ICD (lead implantation time), and the total fluoroscopy time were recorded for each patient. The investigators also measured the ventricular pacing threshold at a 0.5-ms pulse duration, ventricular pacing impedance, and P- and R-wave amplitudes.

Device Programming

The study protocol recommended the use of a lower cutoff rate of 120 or 130 bpm for a VT-1 monitoring zone without therapy. The detection of as many SVT episodes as possible was thus facilitated to compare the efficacy of the SMART detection enhancement algorithm between the 2 groups.

The investigators were free to select the cutoff rates for ICD therapy zones. The tachycardia discrimination algorithm was activated in all VT zones. The VT zone was programmed at 50 bpm above the monitor zone, with a detection duration of 14, onset of 20%, stability of 12%, and SMART detection and redetection on. The detection for the VF zone was programmed to 8 of 12, whereas the rate cutoff could be programmed individually. The postventricular atrial blanking was 16 ms before to 64 ms after a ventricular event. To avoid ventricular pacing, pacing was programmed to a VVI of 40 bpm.

Follow-Up

During follow-up visits at 1, 3, 6, and 12 months after device implantation, ICD interrogation was performed, all documented episodes of SVT or VT/VF were collected, and the need for ICD system revisions was documented, if applicable.

Analysis of Arrhythmia Episodes

All spontaneous tachyarrhythmia episodes stored by the device were classified by authorized participants of each study center as VF, VT, or SVT. Predefined subtypes of SVT were atrial flutter, atrial fibrillation, sinus tachycardia, and other SVT (Figure 2A and 2B). Episodes of VT or VF with concurrent SVT were classified as VT/VF. Episodes other than VT/VF or SVT were excluded from analysis. From all episodes, AEGMs and ventricular intracardiac EGMs were documented.

Blinded to the classification of the on-site investigator, members of the steering committee (C.S., M.Z., M.N.) of the ADRIA study reviewed a sample of 370 randomly chosen episodes from 85 patients. The concordance of the classification for VT/VF or SVT between the investigators and the committee was 96.5%. The committee thereafter recommended that the on-site rhythm classifications should be generally accepted but reserved the right to overrule on-site decisions if errors were noticed during analysis of the documentation for the episodes.

Specificity and sensitivity of the SMART discrimination algorithm were calculated in all episodes documented in the VT zone. The specificity of the discrimination algorithm was defined as the proportion of correctly classified SVT episodes: true-negative/(true-negative + false-positive). The sensitivity was defined as the proportion of correctly classified VT/VF episodes: true-positive/(true-positive + false-negative).

To account for the bias in deriving specificity and sensitivity from multiple episodes of the same type in individual patients, the results were corrected by the generalized equation estimation (GEE).12,13 In brief, the GEE method adjusts the effective number of episodes of every individual patient, depending on the correlation of the patient’s episodes, which are not necessarily independent. The GEE method is applied before the individual specificity figures are pooled and is generally accepted to provide the best estimate of the true specificity and sensitivity.
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cases, statistical significance was established with according to Pearson or Fisher’s exact test, as appropriate. In all

t-sided Wilcoxon-Mann-Whitney U test was used for normally distributed data, and the rank test was used for data that were not

Statistical analysis of study results was performed with the SPSS software packages 16.0 and PASW Statistics 17.0 (for GEE) (SPSS

Top line is the annotated marker channel; middle line, atrial channel; and bottom line, ventricular channel.

Statistics

Statistical analysis of study results was performed with the SPSS Inc, Chicago, IL). Continuous variables are reported as mean±SD. The 2-sided \( t \) test was used for normally distributed data, and the Wilcoxon-Mann-Whitney \( U \) rank test was used for data that were not distributed normally. Categorical data were compared with a \( \chi^2 \) test according to Pearson or Fisher’s exact test, as appropriate. In all cases, statistical significance was established with \( P<0.05 \).

Per-protocol analysis was performed. Crossover was not allowed. Patients who received a device that was not compatible with their randomization scheme during follow-up were considered dropouts. Arrhythmia episodes and adverse events that had occurred before dropout were taken into account.

The necessary sample size to compare the specificities of the study groups was determined to reject the null hypothesis of inferiority of the A+ ICD specificity with a \( \Delta \geq 7\% \). It was assumed that the specificity in both study groups was 93% (unpublished data from nonrandomized studies available during study planning). With an \( \alpha=0.05 \) and a power of 0.8, we calculated that we would need 181 uncorrelated SVT episodes per group, including a 10% dropout rate. We assumed an interclass correlation of 0.5 between episodes in individual patients and expected 3 episodes per patient. We calculated that it would be possible to disprove the null hypothesis with 120 patients per group.

Results

Patient Population

Of the 265 enrolled patients, 16 (6%) were excluded for violation of randomization or withdrawal of informed consent before implantation. Of the remaining 249 patients, 124 were randomized to the A+ ICD and 125 to the DR-ICD study arm. There were no significant differences in baseline characteristics between the 2 groups, except for the presence of previous myocardial infarction (47% in DR-ICD vs 33% in A+ ICD) and the use of statins (65% in DR-ICD vs 43% in A+ ICD; Table 1). Seventy-three percent of the patients had ischemic heart disease and 39%, a history of VF or VT. The pattern of medication use was typical for a contemporary ICD population, with a high percentage of \( \beta \)-blocker, angiotensin-converting enzyme inhibitor, and diuretic use.

Implantation

The ICD leads implanted in the A+ ICD group were Biotronik Kainox A+ (n=58) and Biotronik Kentrox A+ (n=66). In the DR-ICD group, the ventricular ICD leads were Biotronik Kainox (n=6), Biotronik Kentrox (n=69), Biotronik Linox (n=38), and other ICD leads (n=12), and the atrial leads implanted were the Biotronik Setrox (n=45), Biotronik Selox (n=44), Biotronik Elox (n=3), Medtronic Capsure 5076 (n=28), or other leads (n=5). The mean total implantation time was significantly shorter in the A+ ICD

Table 1. Baseline Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>A+ ICD (n=124)</th>
<th>DR-ICD (n=125)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>12 (10)</td>
<td>20 (16)</td>
<td>NS</td>
</tr>
<tr>
<td>Mean±SD age, y</td>
<td>62±11</td>
<td>63±11</td>
<td>NS</td>
</tr>
<tr>
<td>History of tachyarrhythmia, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VF</td>
<td>12 (10)</td>
<td>11 (9)</td>
<td>NS</td>
</tr>
<tr>
<td>VT without VF</td>
<td>37 (30)</td>
<td>36 (29)</td>
<td>NS</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>22 (18)</td>
<td>16 (13)</td>
<td>NS</td>
</tr>
<tr>
<td>Atrial flutter</td>
<td>7 (6)</td>
<td>2 (2)</td>
<td>NS</td>
</tr>
<tr>
<td>Ischemic heart disease, n (%)</td>
<td>86 (69)</td>
<td>95 (76)</td>
<td>NS</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>41 (33)</td>
<td>59 (47)</td>
<td>0.023</td>
</tr>
<tr>
<td>PTCA</td>
<td>50 (40)</td>
<td>56 (45)</td>
<td>NS</td>
</tr>
<tr>
<td>CABG</td>
<td>13 (10)</td>
<td>21 (17)</td>
<td>NS</td>
</tr>
<tr>
<td>Nonischemic cardiomyopathy, n (%)</td>
<td>27 (22)</td>
<td>26 (21)</td>
<td>NS</td>
</tr>
<tr>
<td>Valvular disease, n (%)</td>
<td>12 (10)</td>
<td>12 (10)</td>
<td>NS</td>
</tr>
<tr>
<td>NYHA functional class, I/II/III/IV, n</td>
<td>17/47/20/0</td>
<td>16/38/31/4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Patients with information on medication, n (%)*</td>
<td>119 (96)</td>
<td>120 (96)</td>
<td>NS</td>
</tr>
<tr>
<td>( \beta )-blocker</td>
<td>109 (92)</td>
<td>112 (93)</td>
<td>NS</td>
</tr>
<tr>
<td>ACE inhibitor</td>
<td>98 (82)</td>
<td>95 (79)</td>
<td>NS</td>
</tr>
<tr>
<td>Angiotensin II antagonist</td>
<td>13 (11)</td>
<td>20 (17)</td>
<td>NS</td>
</tr>
<tr>
<td>Diuretic</td>
<td>86 (72)</td>
<td>88 (73)</td>
<td>NS</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>35 (28)</td>
<td>38 (30)</td>
<td>NS</td>
</tr>
<tr>
<td>Other antiarrhythmic drugs</td>
<td>2 (2)</td>
<td>3 (2)</td>
<td>NS</td>
</tr>
<tr>
<td>Lipid-lowering therapy</td>
<td>51 (43)</td>
<td>78 (65)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>22 (18)</td>
<td>35 (29)</td>
<td>NS</td>
</tr>
<tr>
<td>Thrombocyte aggregation inhibitor</td>
<td>89 (75)</td>
<td>99 (83)</td>
<td>NS</td>
</tr>
<tr>
<td>Digitals</td>
<td>24 (20)</td>
<td>31 (26)</td>
<td>NS</td>
</tr>
</tbody>
</table>

PTCA indicates percutaneous transluminal coronary angioplasty; CABG, coronary artery bypass graft; NYHA, New York Heart Association; ACE, angiotensin-converting enzyme; and NS, not significant.

*Percentage of patients taking a certain drug was calculated among 239 patients (96%) with information on medication.
Follow-Up and Adverse Events

The mean follow-up was 370±104 days, with a cumulative follow-up of 251 years. Thirteen patients (5%) died. None of these deaths were device related. Fifteen patients (6%) were lost to follow-up. Arrhythmia episodes and adverse events that had occurred before dropout were included in the analysis. There were 23 system-related adverse events requiring reintervention (Table 3). These included high defibrillation thresholds with the initial lead during implantation or predischarge testing (A+ICD group n=2, DR-ICD group n=1), atrial lead dislocation (DR-ICD group n=5), or repositioning of the ventricular lead because of dislocation or high pacing thresholds (A+ICD group n=7, DR-ICD group n=5). Of the 3 patients with high defibrillation thresholds, 1 patient in the DR-ICD arm received a high-energy device, and an additional superior vena cava (SVC) coil was implanted in a patient in the A+ group. Another patient in the A+ group received a dual-coil lead along with a single-chamber VVI-ICD and was hence counted as a dropout.

Documented Episodes

A total of 3498 spontaneous episodes of arrhythmia were recorded. Sixty-four supraventricular episodes were excluded because the tachycardia discrimination algorithm had been switched off by the investigators because of small atrial signals or permanent atrial arrhythmias (A+ICD group n=7, DR-ICD group n=2; P=NS). Another 224 episodes (154 episodes in 20 patients in the DR-ICD group and 70 episodes in 14 patients in the A+ICD group, P=NS) were excluded because the investigators classified them as “other rhythm” or “unclear” (mostly owing to intermittent T-wave oversensing or premature ventricular contractions).

Of the remaining 3210 episodes, 1894 occurred in the A+ICD group and 1316 in the DR-ICD group. This difference was not statistically significant after correction by the GEE method (P=0.09). In total, 18.5% of episodes were VT or VF and 81.5% were SVT. The distribution of ventricular and supraventricular arrhythmias was comparable in both groups, except for a slightly higher number of VT episodes in the A+ICD group. During data analysis, 21 (0.7%) episode classifications made by the investigators were overruled by the steering committee. Table 4 compares rhythm classification for the 2 randomized groups.

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**Table 2. Implantation Data**

| Variable | A+ICD (n=124) | DR-ICD (n=125) | P  
|----------|---------------|---------------|---
| Total implantation time, min | 67±30 | 79±30 | 0.003 
| Lead implantation time, min | 26±19 | 36±19 | <0.001  
| Fluoroscopy time, min, s | 6’, 15”±6’, 31” | 6’, 59”±5’, 41” | NS  
| Atrium | | | NS  
| P-wave amplitude, mV | 3.5±0.8 | 3.2±0.6 | NS  
| Pt, W | ... | 650±133 | ...  
| Ventricle | | | NS  
| R-wave amplitude, mV | 11±2 | 11±2 | NS  
| PT in all leads, V at 0.5 ms | 1.2±1.0 | 0.8±0.6 | <0.001  
| PT in Kentrox leads, V at 0.5 ms* | 0.7±0.5 (n=65) | 0.8±0.4 (n=69) | NS  
| Pt in all leads, W | 759±297 | 880±292 | 0.002 
| Pt in Kentrox leads, W* | 955±276 (n=65) | 912±311 (n=69) | NS  

*Newer technology, with a smaller surface area of the ventricular tip electrode (1.8 mm²).

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**Table 3. Adverse Events During Implantation and Follow-Up**

| Event | A+ICD (n=124) | DR-ICD (n=125) | P  
|-------|---------------|---------------|---
| Follow-up duration, mean±SD, d | 361±104 | 379±106 | NS  
| Deaths, n (%) | 6 (4.8) | 7 (5.6) | NS  
| Device related | 0 | 0 | NS  
| Cardiac* | 2 (1.6) | 4 (3.2) | NS  
| Noncardiac* | 4 (3.2) | 3 (2.4) | NS  
| Dropout, n (%) | 9 (7.3) | 6 (4.8) | NS  
| Late informed consent withdrawal | 0 | 1 (0.8) | NS  
| Lost to follow-up or poor compliance | 5 (4.0) | 5 (4.0) | NS  
| Received new device (lead or ICD)† | 4 (3.2) | 0 | NS  
| Adverse events (invasive solution), n (%) | 10 | 13 | NS  
| Failure to defibrillate (implantation, predischarge) | 1 | 1 | NS  
| Ventricular perforation | 0 | 1 | NS  
| Pneumothorax | 1 | 1 | NS  
| Atrial lead dislocation | ... | 5 | ...  
| Ventricular lead dislocation or high threshold | 7 | 5 | NS  

*Confirmed or assumed to have this cause.  
†In 2 cases, switch to a conventional ICD lead was required because of dislocation or a high pacing threshold with the Kainox A+ lead: in 1 patient, a high-energy device was used during implantation, and in 1 patient, upgrade to cardiac resynchronization therapy was performed.
The proportion of the different arrhythmias at different rates is illustrated in Figure 3. The large number of sinus tachycardia episodes (61%) was due to the intentionally low cutoff rate for the VT-1 zone. The programmed lower cutoff rate for VT-1 was 130 bpm (as recommended in the study protocol) in 58.4% of all episodes, between 131 and 140 bpm in 29.2% of episodes, and 140 bpm in 12.3%.

**Sensitivity and Specificity**

All 593 spontaneous episodes classified by the investigators as VF or VT were correctly discriminated, resulting in a sensitivity of 100% for both groups before and after GEE correction. Of the 2617 SVT episodes, 2564 were detected within the VT rate range and were therefore evaluated by the tachycardia discrimination algorithm and included in our specificity calculations in Table 5. The GEE-corrected specificity did not differ between the A+-ICD group (61.8%) and the DR-ICD group (66.2%, P=0.22); however, the null hypothesis of inferiority of the A+ specificity cannot be rejected (P=0.39). The overwhelming majority of SVT episodes were sinus tachycardia. We therefore analyzed a sample of 492 false-positive sinus tachycardia episodes. False-positive detection typically resulted from early premature ventricular contractions, activating the onset criterion or intermittent atrial sensing disturbances. Both over- and under-sensing in the atrium rendered the algorithm to assume different averaged rates in the atrium versus ventricle, precluding proper detection of sinus tachycardia. Whereas the prevalence of premature ventricular contractions was similar in both study arms, over- and under-sensing of atrial signals was more often found in the A+-ICD group. Episodes of over- or under-sensing were found in 23 of 63 (36%) A+-ICD patients with sinus tachycardia, compared with 5 of 47 (11%) DR-ICD patients with sinus tachycardia (P=0.002). This was due to the higher prevalence of small atrial signals before amplification in the A+-ICD group, which can cause P-wave undersensing or far-field R-wave oversensing and may explain the slight difference between the specificities of the study groups. Typical examples of complete undersensing of the atrial signal (Figure 4A) and intermittent R-wave oversensing (Figure 4B) in the monitor zone did not result in untoward clinical consequences for the patient.

Despite misclassification of the SVT episodes, only a very few patients received shock therapy, either because the vast majority of episodes was in the monitor zone or the SVT terminated before shock delivery. In only 46 of 1126 false-positive episodes in the VT or VF zone (4.1% not GEE corrected) were shocks were delivered. Thirty-four episodes occurred in 7 patients of the A+-ICD group, and 12 episodes occurred in 7 patients of the DR-ICD group.

**Discussion**

This is the first study to compare a novel, single-lead ICD system with atrial sensing capabilities to a conventional...
dual-chamber ICD. The main finding is that in patients with standard ICD indications and no need for antibradycardia pacing, the A+ICD system is faster to implant and noninferior with regard to VT and SVT detection and therapy when compared with a DR-ICD system. It provides an attractive alternative to an additional atrial lead if one wishes to obtain an AEGM in ICD patients.

Need for Atrial Sensing
In the contemporary ICD population, the majority of patients do not require antibradycardia pacing. The DAVID trial demonstrated that right ventricular pacing even increases mortality and hospitalization rate in an ICD population and should therefore be avoided.6 In the cardiac resynchronization therapy population, even right atrial pacing may have undesirable effects.14 Although pacing should be avoided whenever possible, sensing information from the atrium is desirable for numerous reasons. First, the integration of atrial sensing information can be crucial in differentiating supraventricular from ventricular arrhythmias. Inappropriate shocks not only impair quality of life but also are associated with increased mortality and should thus be avoided by all means.15 Currently, all manufacturers feature detection enhancement algorithms that achieve high sensitivities and specificities and often integrate a comparison of ventricular and atrial signals.11,16,17 The SMART detection algorithm used in this study has been described elsewhere and has been shown to have a sensitivity of 100%, along with a specificity of 89%.11 In our study, the sensitivity was 100%; that is, all ventricular tachyarrhythmias were detected as such, whereas the overall specificity was only 64%. The specificity of a detection enhancement algorithm depends on numerous parameters, such as the population studied, the prevalence of SVTs, and device programming. Hence, it is difficult to compare these algorithms if they are not studied under the same conditions. The relatively low specificity in the present study may be explained by the fact that the rate cutoff was unusually low, at 130 bpm, to obtain as many episodes as possible. With faster heart rates, the impact of premature ventricular contractions on triggering the onset criterion should decrease. In fact, analysis of a nonprespecified small sample of 321 episodes recorded in 21 patients in whom the cutoff had been set to ≥140 bpm resulted in a GEE-corrected specificity of 86%, a specificity reported earlier.11 It is therefore likely that the lower specificity stems from an unusually low study cutoff and not from a performance problem of the SMART algorithm.

Another important reason for the acquisition of atrial information is the possibility to diagnose atrial fibrillation and to initiate anticoagulant and possibly antiarrhythmic therapy. A recent study using remote monitoring found that 13% of a contemporary pacemaker, ICD, and cardiac resynchronization therapy population had previously unknown atrial fibrillation.18 Thus, the availability of an AEGM in combination with remote monitoring may offer accelerated treatment options for these patients, for instance, the potential to reduce strokes.19

Implantation and Complications
Not surprisingly, the use of a single-lead ICD resulted in shorter total implantation times owing to shorter lead implantation time. The use of the single-coil ICD A+ defibrillation lead did not result in a significantly higher failure to defibrillate rate when compared with the dual-coil leads. Although dual-coil defibrillator leads offer more flexibility in the choice of the shock pathway in the rare case of high defibrillation thresholds, randomized trials showed either no difference20 or only a small difference (10.2 vs 9.8 J)21 in the defibrillation threshold between single- and dual-coil ICDs.

Table 5. Discrimination Algorithm Results and GEE-Corrected Specificity

<table>
<thead>
<tr>
<th></th>
<th>A+/ICD</th>
<th>DR-ICD</th>
<th>P</th>
<th>All Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>VF or VT, n</td>
<td>328</td>
<td>265</td>
<td>NS</td>
<td>593</td>
</tr>
<tr>
<td>True-positive</td>
<td>328</td>
<td>265</td>
<td></td>
<td>593</td>
</tr>
<tr>
<td>False-negative</td>
<td>0</td>
<td>0</td>
<td></td>
<td>0</td>
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<tr>
<td>Sensitivity, %</td>
<td>100</td>
<td>100</td>
<td>NS</td>
<td>100</td>
</tr>
<tr>
<td>SVT, n</td>
<td>1521</td>
<td>1043</td>
<td>NS</td>
<td>2564</td>
</tr>
<tr>
<td>True-negative</td>
<td>830</td>
<td>663</td>
<td></td>
<td>1493</td>
</tr>
<tr>
<td>False-positive</td>
<td>691</td>
<td>380</td>
<td></td>
<td>1071</td>
</tr>
<tr>
<td>Specificity, %</td>
<td>61.8</td>
<td>66.2</td>
<td>NS</td>
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<tr>
<td>Lower 95% Cl bound, %</td>
<td>55.7</td>
<td>59.4</td>
<td>NS</td>
<td>60.0</td>
</tr>
<tr>
<td>Upper 95% Cl bound, %</td>
<td>67.9</td>
<td>72.9</td>
<td></td>
<td>69.1</td>
</tr>
</tbody>
</table>

Figure 4. EGMs recorded by an A+/ICD, with examples of complete atrial undersensing (A) and intermittent, atrial R-wave oversensing (B); 25 mm/s. Top line is the annotated marker channel; middle line, atrial channel; and bottom line, ventricular channel.
Atrial lead dislodgement occurred in 4% of the patients in the DR-ICD group, which is slightly lower than in previously reported large series.20 Naturally, this complication cannot occur in the A+/ICD group. In the A+/ICD group, the ventricular pacing threshold was slightly higher than in the DR-ICD group, which was entirely due to the initial higher usage of the older-generation Kainox A+ leads. For safety purposes, this first pentapolar lead had a relatively large surface area (6.0 mm²) to minimize the risk of perforation. Based on clinical experience, its successor, the Kentrox A+ lead, had a much smaller surface area (1.8 mm²). After exclusion of the Kainox A+ leads, the ventricular pacing thresholds did not differ between the 2 groups. The 12-month mortality rate of 5.2% is consistent with those in other ICD studies.1

Difference to VDD Pacemaker Sensing Algorithms
The concept of single-lead VDD pacing systems with a floating bipolar in the atrium has long been available but comprises only 7% of the European pacing market.21 One reason for the reluctance to use VDD pacing is concern for the development of sinus node disease, with a subsequent need for pacing. Schaer and colleagues22 demonstrated in a large cohort of 320 patients with atrioventricular nodal disease that only 1% required an upgrade to a DDD pacemaker during follow-up. Intermittent atrial undersensing during deep breathing, change of body position, or exercise is a well-known phenomenon that occurs in both VDD and DDD pacemaker systems.21 The incidence of atrial undersensing in VDD systems is between 5% and 7% but is clinically silent in the vast majority of patients.21–25 During follow-up, the amplified atrial sensing signal remained stable and showed no tendency for deterioration in the A+/ICD group. The processing of the atrial signal differs between VDD pacemakers and the studied ICD, because the latter comprises a special input stage that amplifies the atrial signal up to 4-fold.

Limitations
This study focused on atrial sensing and its contribution to rhythm discrimination in an ICD. Its impact on atrioventricular sequential pacing was not evaluated in this study. Second, our study was not designed to investigate the influence of sensing disturbances on discrimination or to provide a mechanistic explanation of SVT discrimination failure. Third, the performance of the A+ single-coil ICD lead may be different in the case of a right-sided implant. Because all of our implantations were performed from the left side, our study does not provide any data for that setting. However, data from VDD pacemaker studies have actually shown even better atrial sensing behavior in right-sided implants.20 Fourth, with the devices used in this study, atrial tachyarrhythmias were recorded only if their ventricular rate was above the VT cutoff rate. Because atrial tachyarrhythmias with a slow ventricular rate have been missed, the information obtained from the devices studied has not been validated for the further therapeutic management of patients with suspected atrial tachyarrhythmias. Finally, it cannot be completely ruled out that the observed higher incidence of atrial over- or under-sensing in the A+/ICD group can be clinically significant in patients with slow VTs and concomitant sinus tachycardia.

Conclusion
The use of an A+ single-coil ICD lead in defibrillator patients without a requirement for pacing is a clinically elegant means to obtain AEGMs from only 1 lead. Compared with ICD patients with an additional atrial lead, this results in shorter implantation times without sacrificing the accuracy of arrhythmia detection.

Appendix: Participating Centers and Investigators
University Hospital, Basel, Switzerland: Christian Sticherling, MD; Beat Schaer; MD; Heart Center, University of Göttingen, Göttingen, Germany: Markus Zabel, MD; Dieter Zenker, MD; Charité, Campus Benjamin Franklin, Berlin, Germany: Sebastian, Spenceker, MD; Schwarzwald-Baar-Klinikum, Villingen-Schwenningen, Germany: Udo Meyerfeldt, MD; Hannover Medical School, Hannover, Germany: Michael Niehaus, MD; University Hospital of Muenster, Germany: Lars Eckardt, MD; Julia Koebe, MD; Vivantes-Humboldt Klinikum, Berlin, Germany: Steffen Behrens, MD; St.-Johannes Hospital, Dortmund, Germany: Ralf Dedner, MD; Sana Klinikum, Berlin, Germany: Olaf Göing, MD; and Cardiology Practice, Bonn, Germany: Thomas Klingelenben, MD.

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Disclosures
Dr Sticherling is a consultant for Biotronik, Medtronic, and Boston Scientific. Dr Zabel is a consultant for Biotronik, Medtronic, and Boston Scientific. Dr Spenceker is a consultant for Biotronik and Medtronic. Dr Niehaus is a consultant for Medtronic and Boston Scientific. The other authors report no potential conflicts.

References


Supraventricular tachyarrhythmias are a frequent cause for inappropriate therapy in patients with implantable cardioverter-defibrillators. Atrial sensing and electrogram recordings are potentially helpful to discriminate supraventricular from ventricular tachycardias. The present study compared a novel, implantable cardioverter-defibrillator system that incorporates an atrial sensing bipolar in the single implantable cardioverter-defibrillator lead (A+ICD, 124 patients) with a conventional, dual-chamber implantable cardioverter-defibrillator system with a separate atrial lead (125 patients) in patients without bradycardia pacing indications. Both systems correctly identified all ventricular tachycardia episodes, and supraventricular tachyarrhythmia discrimination with the A+ system was not inferior to that of the conventional system. The A+ system was faster to implant. This single-lead system offers potentially useful atrial sensing without the need to implant an additional atrial lead.

CLINICAL PERSPECTIVE

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Christian Sticherling, Markus Zabel, Sebastian Spencker, Udo Meyerfeldt, Lars Eckardt, Steffen Behrens, Michael Niehaus and for the ADRIA Investigators

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