T-Wave Oversensing in Patients With Brugada Syndrome: True Bipolar Versus Integrated Bipolar Implantable Cardioverter Defibrillator Leads

Multicenter Retrospective Study

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Background—It is thought that dedicated bipolar are more susceptible to T-wave oversensing when compared with integrated bipolar leads. This could be of extreme importance in patients with Brugada syndrome (BrS) because T-wave oversensing in this population is more frequent when compared with other implantable cardioverter defibrillator (ICD) recipients without BrS. We aimed to compare the incidence of T-wave oversensing in patients with BrS according to the type of lead (integrated bipolar versus true/dedicated bipolar).

Methods and Results—All patients diagnosed with BrS with an ICD implant in 10 tertiary hospitals between 1993 and 2013 were included in the study. A total of 480 patients were included (mean age, 45.6±14 years). During a mean follow-up of 74.9±51.7 months (median, 69; range, 2–236), 28 patients had T-wave oversensing (5.8%), leading to inappropriate shock in 18 (3.8%). All these events occurred in patients with true bipolar ICD leads ($P=0.01$) and in 2 patients it was solved instantaneously by changing the configuration from a dedicated to an integrated bipolar sensing configuration. In the stepwise multivariate models, only integrated bipolar ICD leads (hazard ratio, 0.34; 95% confidence interval, 0.171–0.675; $P=0.002$) was independent predictor of non–T-wave oversensing.

Conclusions—T-wave oversensing is a potential reason of inappropriate shocks in patients with BrS receiving ICDs. In the vast majority it can be solved by reprogramming. However, in some patients it still requires invasive intervention. Importantly, incidence is significantly lower using an integrated bipolar lead system when compared with a dedicated bipolar lead system and hence the latter should be routinely used in BrS cases. (Circ Arrhythm Electrophysiol. 2015;8:792-798. DOI: 10.1161/CIRCEP.115.002871.)

Key Words: arrhythmias, cardiac ■ Brugada syndrome ■ defibrillators, implantable ■ electric countershock ■ follow-up studies

Brugada syndrome (BrS) is an arrhythmogenic disease characterized by an ECG pattern of right bundle-branch block, ST-segment elevation in the right precordial leads, and an increased risk of sudden cardiac arrest as a result of polymorphic ventricular tachyarrhythmias or ventricular fibrillation (VF).1 Patients with BrS implanted with an implantable cardioverter defibrillator (ICD) have nearly twice the rate of inappropriate shocks when compared with appropriate shocks.2 One of the potential reasons for inappropriate shocks in this population is T-wave oversensing. Sensing of the ICD can either be dedicated bipolar or be integrated bipolar. It is thought that true bipolar leads are more susceptible to T-wave oversensing.
WHAT IS KNOWN

• One of the main reasons for inappropriate shocks in patients with Brugada syndrome is because of T-wave oversensing. Modern integrated bipolar and dedicated bipolar leads have similar performance for sensing ventricular fibrillation, but they differ in their susceptibility to oversensing.

WHAT THE STUDY ADDS

• We found that incidence of T-wave oversensing is significantly lower using an integrated lead system when compared with a dedicated or true bipolar lead system in patients with Brugada syndrome receiving implantable cardioverter defibrillators. Programming of the ventricular sensing configuration should be performed with recognition of the possibility of T-wave oversensing.

oversensing when compared with integrated bipolar leads, probably because of greater variations in R-wave amplitude. This could be of extreme importance in BrS because T-wave oversensing in this population has been reported to be more frequent.

We aimed to compare the incidence of T-wave oversensing in patients with BrS according to the type of ICD lead (integrated bipolar [coil plus distal lead electrode] versus dedicated bipolar).

Methods

All patients diagnosed with BrS and implanted with an ICD in 10 tertiary hospitals between 1993 and 2013 were included in the study. The diagnosis was made after an episode of aborted sudden cardiac arrest, during evaluation of syncope, in asymptomatic patients with a suggestive ECG pattern recorded during routine examination, or as a consequence of familial screening after the diagnosis of BrS in a family member. This registry was approved by the institutional review committee, and the subjects gave informed consent.

Patients were included in the study if they had a type 1 Brugada pattern on ECG at baseline on at least 1 occasion or after provocation with a class I antiarrhythmic drug (determined by its availability in the participating hospitals: ajmaline, pilsicainide, flecainide, or procainamida procainamide. A type 1 ECG was defined as a prominent coved ST-segment elevation displaying J-wave amplitude or ST-segment elevation ≥0.2 mV at its peak followed by a negative T wave. T-wave oversensing was defined as an artifact present with each R wave after a relatively fixed interval (Figure 1). Echocardiography was performed in all the patients to rule out underlying structural heart disease.

The following clinical data were collected: circumstances of diagnosis, indication for ICD implantation, age at diagnosis, sex, family history of sudden cardiac death (before the age of 45 years), results of pharmacological testing for unmasking the characteristic coved-type ECG pattern, appropriate shocks in the long-term follow-up (defined as shocks or antitachycardia pacing delivered for ventricular arrhythmias), inappropriate shocks (which included T-wave oversensing, supraventricular tachycardia or atrial fibrillation, lead fracture, noise and sinus tachycardia), and finally brand of lead and ICD.

In the absence of symptoms or device therapy, patients were seen routinely every 3 to 6 months for clinical review and device interrogation, according to local practice, and every 6 to 12 months for patients with ICD remote monitoring capabilities. ICD programming was at the discretion of the referring electrophysiologist, but after 2006 recommendations,6 programming a single VF zone above 210 to 220 beats per minute was suggested.

In the event of a shock, the patient was seen at the ICD clinic within 24 hours, and the device was interrogated. Only the first appropriate therapy, the first inappropriate shock, and the first lead failure were considered for analysis.

Statistical Analysis

Continuous variables are reported as mean±SD. Categorical variables are stated as absolute and relative frequencies. A comparison of baseline characteristics between groups (integrated bipolar versus dedicated bipolar) was performed with the 2-sided t test (in normally distributed variables) or Mann–Whitney U test (non-normally distributed variables). All statistics were computed with SPSS software version 21 (SPSS Inc, Chicago, IL). All tests were 2-tailed, and a P value of <0.05 was considered to indicate statistical significance.

Figure 1. Example of inappropriate shock because of T-wave oversensing (arrows) in a patient with dedicated bipolar implantable cardioverter defibrillator lead.
To analyze time duration until the occurrence of T-wave oversensing univariable and multivariable Cox proportional hazard regression analysis was used. Only variables with a value of $P<0.20$ in univariable analysis were used for the multivariable analysis. Sex, age, R wave at implant, history of sudden cardiac arrest, spontaneous type 1 ECG, SCN5A mutation status, manufacturer of ICD, type of ICD lead, and finally discrepancy in ICD manufacturer–ICD lead manufacturer were tested in univariable analysis. Only SCN5A mutations, discrepancy in ICD manufacturer–ICD lead manufacturer, and type of ICD lead had a value of $P<0.20$.

All authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the article as written.

## Results

### Clinical Characteristics and Indication for ICD Implantation

Patient characteristics are summarized in Table 1. Briefly, they were predominantly men (76%), with a mean age of 45±14 years, mostly with syncope history (51%) and with a mean sensed R wave of 10.5±3.8 mV. Main baseline characteristics did not differ significantly between patients with true versus integrated bipolar ICD leads except for higher prevalence of baseline type 1 Brugada pattern (Table 2). Mean follow-up duration was 74.9±51.7 months (median, 69 months; range, 2–236) and was longer in subjects with integrated bipolar ICD leads (97.9±54.1 versus 65.6±47.6 months; $P<0.001$) when compared with patients with true bipolar ICD leads.

### Outcome

During 74.9 months of follow-up, 28 patients (5.8%) presented with T-wave oversensing, leading to inappropriate shock in 18 (3.8%). Interestingly, all these events occurred in patients with dedicated bipolar ICD leads ($P=0.01$). In all but 4 patients, ICD device and the connected ICD lead were from the same manufacturer; of these, 1 patient presented T-wave oversensing with subsequent inappropriate shock (St Jude Medical ICD lead with Biotronik ICD device).

In multivariable analysis, the only factor predictive of inappropriate device discharge was type of ICD lead (hazard ratio, 0.34; 95% confidence interval, 0.171–0.675; $P=0.002$). Spontaneous type 1 ECG, age, sex, discrepancy lead-ICD device, previous sudden cardiac death, and SCN5A mutation status were not predictive in this selected population (Table 3; Figure 2).

About the management of ventricular oversensing, in the vast majority of the patients, ventricular oversensing resolved after device reprogramming (n=21; 75%). Oversensing of T waves in 2 patients with a Medtronic ICD it was solved after changing the sensing configuration, from dedicated to integrated bipolar sensing (Figure 3). In 2 patients, an additional active fixation sense/pace lead was screwed into interventricular septum and connected to sense/pace port of the ICD. In 1

### Table 1. Patient Characteristics

<table>
<thead>
<tr>
<th>Patients (n=480)</th>
<th>Age, y (SD)</th>
<th>Male, n (%)</th>
<th>Female, n (%)</th>
<th>Spontaneous type 1, n (%)</th>
<th>Aborted sudden cardiac death, n (%)</th>
<th>Family history of sudden cardiac death, n (%)</th>
<th>Genetic positive (n=190), n (%)</th>
<th>Syncpe, n (%)</th>
<th>Asymptomatic, n (%)</th>
<th>R wave (implantation, mV; SD)</th>
<th>Remote monitoring, n (%)</th>
<th>True bipolar defibrillator lead, n (%)</th>
<th>Integrated bipolar defibrillator lead, n (%)</th>
<th>Guidant defibrillator, n (%)</th>
<th>Medtronic defibrillator, n (%)</th>
<th>Sorin defibrillator, n (%)</th>
<th>St Jude Medical defibrillator, n (%)</th>
<th>Biotronik defibrillator, n (%)</th>
<th>Discrepancy defibrillator-lead manufacturers, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y (SD)</td>
<td>45.6 ±14.6</td>
<td>364 (75.8%)</td>
<td>116 (24.2%)</td>
<td>204 (42.5%)</td>
<td>45 (9.4%)</td>
<td>74 (15.4%)</td>
<td>52 (27.3%)</td>
<td>246 (51.3%)</td>
<td>189 (39.4%)</td>
<td>10.5 ±3.8</td>
<td>150 (31.3%)</td>
<td>342 (71.3%)</td>
<td>138 (28.8%)</td>
<td>141 (29.4%)</td>
<td>65 (13.5%)</td>
<td>4 (0.8%)</td>
<td>121 (25.2%)</td>
<td>149 (31%)</td>
<td>4 (0.8%)</td>
</tr>
</tbody>
</table>

### Table 2. Baseline Characteristics and Incidence of Events in Dedicated Bipolar vs Integrated Bipolar Implantable Cardioverter Defibrillator Leads

<table>
<thead>
<tr>
<th>Dedicated Bipolar (n=342)</th>
<th>Integrated Bipolar (n=138)</th>
<th>Total (n=480)</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y (SD)</td>
<td>44.5 ±14.6</td>
<td>46.7 ±13.5</td>
<td>45.6 ±14</td>
</tr>
<tr>
<td>Sex (female), n (%)</td>
<td>89 (26%)</td>
<td>27 (19.6%)</td>
<td>116 (24.16%)</td>
</tr>
<tr>
<td>Mean follow-up, mo (SD)</td>
<td>65.6 ±47.6</td>
<td>97.9 ±54.1</td>
<td>74.9 ±51.6</td>
</tr>
<tr>
<td>R wave, mV (SD)</td>
<td>10.5 ±3.5</td>
<td>10.5 ±4.5</td>
<td>10.5 ±3.8</td>
</tr>
<tr>
<td>Previous sudden cardiac arrest (%)</td>
<td>31 (9.1%)</td>
<td>14 (10.1%)</td>
<td>45 (9.4%)</td>
</tr>
<tr>
<td>Type 1 pattern (%)</td>
<td>163 (47.7%)</td>
<td>41 (29.7%)</td>
<td>204 (42.5%)</td>
</tr>
<tr>
<td>Positive genetic, n (%)</td>
<td>34 (29)</td>
<td>18 (24.6%)</td>
<td>52 (27.3%)</td>
</tr>
<tr>
<td>Appropriate shocks, n (%)</td>
<td>49 (14.3%)</td>
<td>25 (18.1%)</td>
<td>74 (15.4%)</td>
</tr>
<tr>
<td>Inappropriate shocks, n (%)</td>
<td>70 (20.5%)</td>
<td>18 (13%)</td>
<td>88 (18.4%)</td>
</tr>
<tr>
<td>T wave oversensing, n (%)</td>
<td>28 (8.2%)</td>
<td>0 (0%)</td>
<td>28 (5.8%)</td>
</tr>
<tr>
<td>Discrepancy, n (%)</td>
<td>4 (1.2%)</td>
<td>0 (0%)</td>
<td>4 (0.8%)</td>
</tr>
</tbody>
</table>
patient a new lead plus ICD device (Medtronic) was implanted because of battery depletion, importantly in this patient sensing was changed from tip to coil without more episodes of T-wave oversensing during the follow-up. In 4 patients repositioning of the right ventricular (RV) lead to obtain ventricular electrograms with higher amplitude R waves (higher R wave:T wave ratios) was necessary to overcome the problem.

Discussion
This retrospective study compared integrated and dedicated/true bipolar RV defibrillator leads with respect to ventricular sensing performance, specifically T-wave oversensing, in a broad cohort of patients with BrS. The main finding was that incidence of T-wave oversensing is significantly lower using an integrated lead system than using a dedicated system. The rate of inappropriate therapy because of T-wave oversensing was 3.8%. In the vast majority of cases, it was solved by reprogramming (including changing the sensing configuration (from dedicated bipolar to integrated bipolar). Hence, at the time of implantation, the physician’s choice of a dedicated or true versus an integrated lead RV should take into account the clinical implications of the performance of the 2 lead designs. After implantation, programming of RV sensing configuration should be performed with the recognition of the possibility T-wave oversensing and its clinical implications.

BrS is an arrhythmogenic disorder with an increased risk of sudden cardiac arrest as a result of polymorphic ventricular tachyarrhythmias or VF.1 Sacher et al2 reported the outcome of patients with BrS implanted with an ICD in a large multicenter registry (n=378; mean follow-up of 77±42 months). They described that patients with BrS implanted with an ICD as having twice the rate of inappropriate shocks (24%) when compared with appropriate shocks (12%) with an overall complication rate of 36%. One of the reasons for inappropriate shocks in this population was because of T-wave oversensing arising from relative changes in R:T ratio leading to double counting on each beat. Sensing of the ICD can either be dedicated bipolar (between the tip electrode and a small ring electrode) or be integrated bipolar (between the tip electrode and RV coil). Modern integrated bipolar and dedicated bipolar leads have similar performance for sensing VF but differ in their susceptibility to oversensing. The larger integrated bipolar antenna is more susceptible to external electromagnetic interference, R-wave double counting, and diaphragmatic myopotentials. Dedicated bipolar leads are more susceptible to T-wave oversensing, probably because of greater variations in R-wave amplitude,3,4 and this could be of extreme importance in patients with hypertrophic cardiomyopathy, dilated cardiomyopathy, cardiac sarcoidosis, long-QT syndrome, familial short-QT syndrome, BrS, and hyperkalemia, in whom T-wave oversensing has been reported to be more frequent.7–11 The cause of this discrepancy has not been clearly elucidated. Some authors concentrate on the measurement properties of the lead system and argue that the quality of the signals recorded by dedicated and integrated bipolar configurations is different.12–14 Requina-Carrion et al15 reported that EGM features can be explained by estimating the extent of myocardium within the range of the lead. They investigated differences in the sensing range of true and integrated bipolar leads by means of bioelectric signal modeling and numeric methods reporting that dedicated bipolar leads

<table>
<thead>
<tr>
<th>Variable</th>
<th>Univariable HR 95% CI P Value</th>
<th>Univariable</th>
<th>Multivariable HR 95% CI P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>1.002 (0.97–1.031) 0.9</td>
<td>Age, y</td>
<td>1.002 (0.97–1.031) 0.9</td>
</tr>
<tr>
<td>Female</td>
<td>0.71 (0.3–1.67) 0.43</td>
<td>Female</td>
<td>0.71 (0.3–1.67) 0.43</td>
</tr>
<tr>
<td>R wave at implant</td>
<td>1.001 (0.89–1.12) 0.9</td>
<td>R wave at implant</td>
<td>1.001 (0.89–1.12) 0.9</td>
</tr>
<tr>
<td>No baseline type 1 pattern</td>
<td>0.9 (0.43–1.92) 0.8</td>
<td>No baseline type 1 pattern</td>
<td>0.9 (0.43–1.92) 0.8</td>
</tr>
<tr>
<td>Previous sudden cardiac arrest (yes)</td>
<td>1.36 (0.40–4.6) 0.6</td>
<td>Previous sudden cardiac arrest (yes)</td>
<td>1.36 (0.40–4.6) 0.6</td>
</tr>
<tr>
<td>Discrepancy</td>
<td>5.002 (0.67–37.2) 0.1</td>
<td>Discrepancy</td>
<td>5.002 (0.67–37.2) 0.1</td>
</tr>
<tr>
<td>Integrated bipolar ICD lead</td>
<td>0.34 (0.175–0.654) 0.001</td>
<td>Integrated bipolar ICD lead</td>
<td>0.34 (0.175–0.654) 0.001</td>
</tr>
<tr>
<td>Positive genetic-SCN5A positive</td>
<td>4.33 (0.58–31.9) 0.1</td>
<td>Positive genetic-SCN5A positive</td>
<td>4.33 (0.58–31.9) 0.1</td>
</tr>
</tbody>
</table>

CI indicates confidence interval; HR, hazard ratio; ICD, implantable cardioverter defibrillator; and TWOS, T-wave oversensing.

Figure 2. Kaplan–Meier curves for freedom of T-wave oversensing according to type of implantable cardioverter defibrillator lead (true vs integrated bipolar).
have a narrower antenna/sensing field/range than integrated bipolar leads. The extent of myocardium within the sensing range of the integrated bipolar lead distributes along the septum and anteriorly, whereas in the case of dedicated bipolar it is localized around the electrode site.

In a direct comparison of the 2 leads, Degeratu et al reported that there were more inappropriate arrhythmia detection (because of lead failure) with dedicated bipolar leads than with integrated bipolar leads (17.8% versus 4.3%). Nevertheless, Freedman et al in a study with 292 patients who were randomly assigned to receive dedicated or integrated bipolar RV leads at the time of cardiac resynchronization therapy–defibrillator implantation reported that integrated bipolar RV defibrillator leads had a significantly lower incidence of RV anodal stimulation when compared with dedicated bipolar RV defibrillation leads, but with no clinically detectable oversensing or undersensing, and with no inappropriate ventricular tachyarrhythmia detections for either lead type. Whether sensing configuration has any relevance in patients with BrS has not been specifically evaluated. However, this is extremely important in these patients because of the fact that T-wave amplitude is significantly higher than that in non-BrS patients.

This question has been specifically addressed in the present study. As we speculated, the use of true bipolar leads in this patient population was associated with a greater incidence of T-wave oversensing than was use of integrated bipolar leads. As a matter of fact, in our series, there was no T-wave oversensing in patients with the latter. Furthermore, as a proof-of-concept, in 2 patients with dedicated bipolar lead, T-wave oversensing disappeared after changing the configuration to integrated bipolar (Figure 3).

Nevertheless, it could be argued that not only the lead has relevance to T-wave oversensing but also the sensing filter or algorithm of the ICD generator. T-wave oversensing can be reduced or avoided via device programming. A band pass filter designed to minimize T-wave oversensing can be used as well as dynamic auto-gain threshold changes; strategies differ by manufacturer. Gilliam reported 2 cases (1 patient with cardiac sarcoidosis and another with dilated myocardiopathy) where T-wave oversensing was corrected by changing only the pulse generator. They first considered that differences in the automatic gain controls of the devices would allow 1 generator to oversense the T waves, whereas the other devices would not. Nevertheless, they pointed out that the 2 were in fact similar in their ability to discriminate between the size of the QRS and T waves. Hence, they concluded that differences in the sensing electrograms recorded by the pulse generators could best be explained by differences in the sensing circuits and not the detection algorithms or automatic gain functions.

Finally, there could also be manufacturer-specific lead/generator compatibility issues that could influence our results. Seegers et al reported that significant manufacturer-related differences exist in the incidence of ventricular oversensing in single- and dual-chamber ICD systems. Specifically, in 4 of 245 patients they identified oversensing problems, three R-wave double-sensing and 1 T-wave oversensing, all of them occurred.
in Biotronik ICDs connected to integrated bipolar ICD leads from other manufacturers. In our series, only 1 patient (of 4 with different ICD device–ICD lead manufacturers) had T-wave oversensing, hence we do not have enough data to rule in or out that hypothesis. To date, it can be concluded that T-wave oversensing is not exclusive to patients with different ICD manufacturer and ICD lead manufacturer combinations.

Limitations
It is likely the true incidence of T-wave oversensing is greater than reported as documented events reflect only those stored in a device memory. Furthermore, this is a retrospective study, and the population included was identified from 10 different centers. Although every effort was made to collect the data in a uniform and thorough manner, some measurement bias may be present. Moreover, because of the retrospective multicenter nature of the study, there was no standardized management of those patients with T-wave oversensing, a reason why dissimilar alternatives to solve the problem were chosen. The range of times from implant to documentation of T-wave oversensing was not available. Furthermore, patient assignment to dedicated bipolar versus integrated bipolar ventricular sensing was according to individual practitioner choice and was not randomized. Finally, ICD programming was also at the discretion of the referring electrophysiologists, and although programming a single VF zone >210 to 220 beats per minute was suggested, there may have been different programming strategies that could have exacerbated the T-wave oversensing.

Conclusions
We found that the incidence of T-wave oversensing is significantly lower using an integrated lead system than using a dedicated or true bipolar lead system in patients with BrS receiving ICDs. Specifically, 3.8% of the patient received inappropriate therapy because of T-wave oversensing. Hence, at the time of implantation, the physician’s choice of a dedicated or true versus an integrated bipolar RV lead should take into account the clinical implications of the performance of the 2 lead designs. After implantation, programming of RV sensing configuration should be performed with the recognition of the possibility T-wave oversensing and its clinical implications.

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References


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