CLINICAL STUDY

Candidacy for a Subcutaneous Implantable Cardioverter Defibrillator in Patients with Cardiac Resynchronization Therapy
Surface Electrocardiogram Screening on the Assumption of the Concomitant Use of the Subcutaneous Implantable Cardioverter Defibrillator and Biventricular Pacing

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Summary

In patients requiring an implantable cardioverter defibrillator (ICD), the combined use of a prior pacemaker and a subcutaneous ICD (S-ICD) could be an alternative treatment option to implantation of new leads or upgrading of pacemakers to an ICD if vascular access is limited. Here, we assessed the prevalence of S-ICD’s eligibility according to surface electrogram screening in those receiving cardiac resynchronization therapy (CRT). S-ICD’s eligibility was assessed in patients with a CRT pacemaker or a CRT defibrillator using the S-ICD template screening tool. Eligibility was defined as fulfillment of the template in both supine and upright positions in one or more leads during biventricular pacing. Among 44 patients (34 men, age: 67 ± 12), 36 (82%) were found to be eligible. The T/QRS amplitude ratio in lead II was significantly lower in those who were eligible (0.31 ± 0.16 versus 0.44 ± 0.18 in the ineligible group, P = 0.04). The lead position, underlying disease, and other electrocardiographic findings were not different between those who were eligible and those who were not. The majority of patients with biventricular pacing were eligible for S-ICD based on current screening tests and may benefit from this treatment. Further study is required.

(Venous stenosis or occlusion is a frequent finding in patients with previously implanted transvenous leads,1-3) making it difficult to implant new leads. Physicians may resort to implanting epicardial leads if venous access is unavailable.

Subcutaneous implantable cardioverter defibrillators (S-ICDs) are a recent development, but they are already widely used. Their effectiveness and safety have been shown in large registries.4,5) S-ICD implantation is less invasive than that of conventional ICDs and is particularly useful for patients with congenitally complex cardiac anatomy or those without venous access.6 One disadvantage, though, is that S-ICDs cannot provide pacing therapy lacking transvenous leads. There have been several case reports of patients with previous transvenous or epicardial pacemakers, in whom S-ICD was newly implanted and used together,7,8 as well as of prior cardiac resynchronization therapy (CRT) with an S-ICD.9 In clinical settings, the number of such patients whose venous access cannot be secured, resulting in no choice other than the concomitant use of pacemakers and S-ICDs, might increase in the future.

The purpose of our study was to go beyond case reporting and assess the proportion of current CRT recipients who are eligible for S-ICD implantation in a moderate-sized patient population. We used surface electrocardiogram (ECG) screening tests to test for S-ICD eligibility as is the current standard.

Key words: Cardiac implantable electronic devices, Combining therapy, Electrocardiographic screening tool, Venous stenosis or occlusion, Previously-implanted transvenous leads, Chronic heart failure

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Methods

Study population: We assessed consecutive patients that had previously received CRT pacemakers (CRT-Ps) or CRT defibrillators (CRT-Ds), who attended routine follow-up at the pacemaker/ICD device clinic in our hospital between February 2016 and March 2017. Demographic data, clinical characteristics, medications, and ultrasound characteristics were obtained from clinical records. ECG parameters were collected from the most recent 12-lead surface ECG.

The study complied with the Declaration of Helsinki. The use of routinely collected anonymous data was ap-
Figure 1. Surface electrocardiogram lead positions during screening for S-ICDs. This figure shows the location of the surface electrodes and S-ICD sensing vectors in the conventional left parasternal and right parasternal configuration. Left-sided parasternal position: LL: in the fifth intercostal space along the left midaxillary line, LA: 1 cm lateral to the left sternal border and 1 cm above the xiphoid process, and RA: 14 cm cranial to electrode LA on the left parasternal line. Electrodes RA and LA on the right-sided parasternal position. LA: 1 cm lateral to the right sternal border and 1 cm above the xiphoid process, RA: 14 cm superior to electrode LA. A ground electrode was placed on a soft tissue location on the right lower extremity. RA indicates right arm; LA, left arm; LL, left leg; and G, ground.

proved by the local ethics committee and was deemed not to require formal patient consent.

Screening for S-ICD eligibility: The Boston Scientific ECG screening tool was used to determine the eligibility for S-ICD in 2 different postures, supine, and upright, during biventricular pacing. As recommended by Boston Scientific, ECG recordings simulating the 3 sensing vectors of the S-ICD were analyzed. The left leg (LL) electrode was placed in the fifth intercostal space along the left midaxillary line, the left arm (LA), 1 cm lateral to the left sternal border and 1 cm above the xiphoid process, and the right arm (RA), 14 cm cranial to the LA electrode (Figure 1). A ground electrode was placed on a soft tissue location on the right lower extremity. The bipolar vector lead I was derived from RA and LA, lead II from RA and LL, and lead III from LA and LL, corresponding to the alternate, secondary, and primary sensing vectors of the S-ICD, respectively. A patient was considered a candidate for S-ICD implant if at least one lead satisfied the S-ICD screening template in both supine and upright positions. The screening protocol was repeated after moving the sternal electrodes (electrodes RA and LA) to the right parasternal line, with electrode LA at 1 cm lateral to the right sternal border and 1 cm above the xiphoid process and electrode RA at 14 cm superior to electrode LA, if the screening failed with the sternal electrodes placed along the left parasternum.

Surface 12-lead ECG analysis: We measured the QRS and the T-wave axes in the patient’s most recent 12-lead surface ECG. The angle between the 2 axes was evaluated as the absolute value of the minor angle. Leads I, II, and aVF were analyzed because these leads mimic the 3 sensing vectors of the S-ICD. The T/QRS amplitude ratio in each of the 3 leads was collected. All ECGs were analyzed by 2 independent electrophysiologists. Reasons for failure were recorded for every single analyzed vector and categorized into high T-wave voltage, high/low QRS complex voltage, and wide QRS complex.

The lead positions of CRT: The position of the RV lead, apex, or septum, was assessed using the procedure record and the patient’s most recent chest X-ray. The position of the LV lead was categorized using chest X-rays. In the posteroanterior view (Figure 2A), the semielliptic shape outlined by the cardiac silhouette was divided into 3 parts along the major axis: the base, the mid, and the apex. In the lateral view (Figure 2B), the semicircle whose straight edge was in the head-tail direction of the body and whose arc was outlined by the posterior cardiac silhouette was divided into 3 pie-shaped parts at intervals of 60°: anterior, lateral, and posterior. The position of the LV lead tip was expressed combining the bidirectional assessments (anterior base, lateral base, etc.) (Figure 2C).

Statistical analysis: Normally distributed continuous variables were expressed as the mean ± standard deviation, and as numbers, and percentages for categorical variables. The differences between the continuous variables were assessed using Student’s t-test. Categorical variables were compared using the χ² test, or Fisher’s exact test when the data are very unequally distributed among the cells of the Table resulting in the expected values in any of the cells of the contingency table being below 5. A multivariable logistic regression analysis was performed to identify the independent clinical predictors of S-ICD’s ineligibility. Statistical significance was defined as P < 0.05. SPSS statistical software (v22, SPSS Inc., Chicago, IL, USA) was used for all statistical analyses.

Results

Study population: A total of 44 consecutive patients (34 men, age: 67 ± 12) were included, comprising 19 patients with dilated cardiomyopathy (DCM), 8 patients with ischemic heart disease, 6 patients with sarcoidosis, 6 patients with valve disease, 2 patients with hypertrophic cardiomyopathy (HCM), and 3 miscellaneous cases. There were 34 patients (77%) with CRT-Ds, whose indication for ICD implantation was primary prevention in 82% and secondary prevention in 18% of the patients.

The RV lead was positioned at the apex in 38 patients and along the septum in 6. The LV lead was positioned in the antero-base in 4 patients, in the antero-mid in 6, in the antero-apex in 1, in the lateral base in 4, in the lateral mid in 10, in the lateral apex in 8, in the postero-mid in 5, and in the postero-apex in 6 (Figure 2C).

Patients’ characteristics are summarized in the Table.

Prevalence of S-ICD’s unsuitability: Overall, a total of 8 (18%) patients were ineligible for S-ICD implantation according to the surface ECG screening criteria during CRT. The 8 patients were distributed over all 6 underlying disease categories (Figure 3), and there was no statistically significant difference in the distribution (P = 0.39).

Among a total of 264 sensing vectors (44 patients × 3 vectors × 2 positions), 108 (41%) were considered inel-
The position of the LV lead. A: In the posteroanterior view of chest X-rays, the semieliptic shape outlined by the cardiac silhouette (indicated by the blue line) was divided into 3 parts along the major axis: the base, the middle, and the apex. The red arrow shows the tip of the LV lead. B: In the lateral view of chest X-rays, the semicircle whose straight edge was in the head-tail direction of the body and whose arc was outlined by the posterior cardiac silhouette (indicated by the blue line) was divided into 3 pie-shaped parts at intervals of 60°: anterior, lateral, and posterior. The red arrow shows the tip of the LV lead. C: The position of the LV lead was divided into 9 parts by the combination of the bidirectional assessments with the number of patients in each position.

Figure 2. The position of the LV lead. A: In the posteroanterior view of chest X-rays, the semieliptic shape outlined by the cardiac silhouette (indicated by the blue line) was divided into 3 parts along the major axis: the base, the middle, and the apex. The red arrow shows the tip of the LV lead. B: In the lateral view of chest X-rays, the semicircle whose straight edge was in the head-tail direction of the body and whose arc was outlined by the posterior cardiac silhouette (indicated by the blue line) was divided into 3 pie-shaped parts at intervals of 60°: anterior, lateral, and posterior. The red arrow shows the tip of the LV lead. C: The position of the LV lead was divided into 9 parts by the combination of the bidirectional assessments with the number of patients in each position.

gible by the screening test. The secondary sensing vector was the most frequently ineligible one (49%), followed by the alternate vector (39%) and the primary sensing vector (35%). The main reason for failure was the high T-wave voltage (76% of sensing vectors), followed by the wide QRS complex (13%), low QRS complex voltage (5.5%), and high QRS complex voltage (5.5%). Figure 4 shows an example of a record that was ineligible because of a wide QRS complex in 2 vectors using the left parasternal placement of sternal electrodes.

In 5 out of the 8 patients who were ineligible for S-ICD implantation, the screening test was performed again after switching electrode placement from the conventional left parasternal position to the right parasternum. However, ECG eligibility did not improve in any patient.

Predictors of eligibility in patients with CRT: The clinical characteristics of the patients who were eligible and ineligible in the left parasternal electrode placement screening were compared (Table). The T/QRS amplitude ratio in lead II was significantly higher in those who were ineligible than in those who were eligible. There was a tendency for a higher T/QRS amplitude ratio in lead aVF and more septal RV lead in the ineligible group, although it did not reach statistical significance. Other baseline characteristics were similar between the groups. In multivariate analysis assessing the T/QRS amplitude ratio in
leads II and aVF and septal RV lead, no variables remained as independent predictors. In a 69-year-old woman with cardiac sarcoidosis (Amplia MRI Quad CRT-D with AdaptivCRT Algorithm, Medtronic Inc., Minneapolis, MN, USA), the ECG screening satisfied S-ICD’s eligibility during the RBBB pattern (QRS width 130 ms in 12-lead ECG), but not during the LBBB pattern (QRS width 161 ms) (Figure 5).

There were 3 patients in whom pacemakers or ICDs with RV leads had been upgraded to CRT-Ps or CRT-Ds. When screening was compared between RV and biventricular pacing, the results were varied: one was eligible in both modes; in another, eligible only in RV pacing; and in the third, eligible only in biventricular pacing.

### Discussion

In this study, based on our single-center experience, S-ICD screening failure occurred in 18% of the current CRT recipients during biventricular pacing. The secondary sensing vector was the one most frequently ineligible.

**Combination therapy with S-ICDs and pacemakers:** S-ICDs are usually not indicated in patients who need anti-bradycardia pacing because no intracardiac leads are placed. On the other hand, they are suited for patients who have limited venous access. It has been reported that venous occlusion is observed in 26-33% of patients with previous transvenous leads of ICDs or pacemakers.\(^{16} \) Prior to our study, there have been some reports of patients with previous transvenous or epicardial pacemakers in whom S-ICD was newly implanted and used together,\(^{20} \) but the clinical experience is still limited. The pooled cohort of the 2 largest S-ICD trials, the Food and Drug Administration-mandated U.S. Investigational Device Exemption (IDE) Registry and the Evaluation of FactOrs ImpacTing CLinical Outcome and Cost EffectiveneSS of the S-ICD (EFFORTLESS S-ICD) registry, excluded patients with unipolar pacemakers or implanted devices that revert to unipolar pacing and included only 19 individuals who had a bipolar pacemaker prior to S-ICD implantation. However, no further details were given regarding those patients.\(^{20} \) In the previous case reports, appropriate sensing by the S-ICD was confirmed during ventricular pacing. It was recommended that bipolar and not unipolar pacing should be used to minimize the pacing artifact on the S-ICD electrograms\(^{20} \) and the detection rate of the S-ICD should be programmed at more than twice the upper pacing rate of the pacemaker.\(^{20} \) van Gelder, et al. reported

### Table: Patients’ Characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Total (n = 44)</th>
<th>Eligible (n = 36)</th>
<th>Ineligible (n = 8)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>67 ± 11</td>
<td>66 ± 12</td>
<td>70 ± 10</td>
<td>0.45</td>
</tr>
<tr>
<td>Male</td>
<td>34 (77%)</td>
<td>27 (75%)</td>
<td>7 (88%)</td>
<td>0.66</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.63 ± 0.10</td>
<td>1.63 ± 0.10</td>
<td>1.63 ± 0.11</td>
<td>1.0</td>
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<tr>
<td>Weight (kg)</td>
<td>60 ± 13</td>
<td>59 ± 13</td>
<td>65 ± 14</td>
<td>0.30</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>22.5 ± 4.1</td>
<td>22.1 ± 4.0</td>
<td>24.3 ± 4.6</td>
<td>0.16</td>
</tr>
<tr>
<td>CRT-P/CRT-D</td>
<td>9/35</td>
<td>5/31</td>
<td>4/4</td>
<td>0.04</td>
</tr>
<tr>
<td>Primary/secondary prevention</td>
<td>28/7</td>
<td>25/6</td>
<td>3/1</td>
<td>0.60</td>
</tr>
<tr>
<td>Hypertension</td>
<td>14 (32%)</td>
<td>10 (28%)</td>
<td>4 (50%)</td>
<td>0.21</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>8 (18%)</td>
<td>7 (19%)</td>
<td>1 (13%)</td>
<td>0.55</td>
</tr>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>38 (86%)</td>
<td>32 (89%)</td>
<td>6 (75%)</td>
<td>0.30</td>
</tr>
<tr>
<td>Antiarrhythmic drugs</td>
<td>32 (73%)</td>
<td>26 (72%)</td>
<td>6 (75%)</td>
<td>0.63</td>
</tr>
<tr>
<td>12-lead ECG</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>QRS width (ms)</td>
<td>157 ± 18</td>
<td>158 ± 15</td>
<td>154 ± 27</td>
<td>0.57</td>
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<tr>
<td>QTc interval</td>
<td>501 ± 28</td>
<td>500 ± 29</td>
<td>506 ± 26</td>
<td>0.60</td>
</tr>
<tr>
<td>QRS axis (degree)</td>
<td>-24 ± 101</td>
<td>-31 ± 97</td>
<td>7 ± 123</td>
<td>0.35</td>
</tr>
<tr>
<td>T-wave axis (degree)</td>
<td>55 ± 57</td>
<td>54 ± 60</td>
<td>63 ± 47</td>
<td>0.69</td>
</tr>
<tr>
<td>The angle between QRS and T-axes (degree)</td>
<td>148 ± 43</td>
<td>145 ± 48</td>
<td>160 ± 18</td>
<td>0.15</td>
</tr>
<tr>
<td>T/QRS amplitude in lead I</td>
<td>0.32 ± 0.30</td>
<td>0.33 ± 0.32</td>
<td>0.29 ± 0.23</td>
<td>0.70</td>
</tr>
<tr>
<td>T/QRS amplitude in lead II</td>
<td>0.33 ± 0.17</td>
<td>0.31 ± 0.16</td>
<td>0.44 ± 0.18</td>
<td>0.04</td>
</tr>
<tr>
<td>T/QRS amplitude in lead aVF</td>
<td>0.31 ± 0.17</td>
<td>0.29 ± 0.15</td>
<td>0.42 ± 0.23</td>
<td>0.056</td>
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<tr>
<td>UCG</td>
<td></td>
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<tr>
<td>LVEF (%)</td>
<td>33 ± 11</td>
<td>33 ± 12</td>
<td>36 ± 12</td>
<td>0.46</td>
</tr>
<tr>
<td>LVDD (mm)</td>
<td>65 ± 10</td>
<td>66 ± 10</td>
<td>63 ± 10</td>
<td>0.43</td>
</tr>
<tr>
<td>Xp</td>
<td>54 ± 7</td>
<td>53 ± 7</td>
<td>54 ± 4</td>
<td>0.74</td>
</tr>
<tr>
<td>Lead position</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RV lead (apex/septum, n)</td>
<td>38/6</td>
<td>33/3</td>
<td>5/3</td>
<td>0.06</td>
</tr>
<tr>
<td>LV lead in PA view (base/mid/apex, n)</td>
<td>8/21/15</td>
<td>7/16/13</td>
<td>1/5/2</td>
<td>0.65</td>
</tr>
<tr>
<td>LV lead in lateral view (anterior/posterior, n)</td>
<td>11/22/11</td>
<td>10/17/9</td>
<td>1/5/2</td>
<td>0.63</td>
</tr>
<tr>
<td>LV lead (A-b-A/m/A-a-L/b-L-m/L-aF-bP-m/P-a, n)</td>
<td>4/4/0/6/10/5/1/8/6</td>
<td>4/3/0/5/7/1/1/5/1/1/1</td>
<td>0.94</td>
<td></td>
</tr>
</tbody>
</table>

Values are shown as the mean ± SD, or n (%). A- indicates antero; -a, apex; -b, base; BMI, body mass index; CRT-P/D, cardiac resynchronization therapy-pacemaker/defibrillator; CTR, cardiothoracic ratio; ECG, electrocardiogram; L-, latero; LV, left ventricle; LVDD, left ventricular internal dimension in diastole; LVEF, left ventricular ejection fraction; -m, mid; P-, postero; PA, posteroanterior; QTc, corrected QT; RV, right ventricle; UCG, ultrasound cardiography; and Xp, X-ray photograph.
Figure 3. The prevalence of S-ICD according to the underlying diseases. There were no significant differences in the prevalence of S-ICD’s unsuitability among the underlying diseases.

Figure 4. Example of surface electrocardiographic screening in a patient with DCM. The left ECG shows the 12-lead ECG and the right ECGs show the screening vectors of leads I through III in supine and upright positions.

an inappropriate shock due to triple counting caused by a wide-paced QRS complex with double R-wave counting and additional T-wave sensing in a patient with an S-ICD and a pacemaker, which was corrected by implantation of a second CS lead and bifocal pacing. Extensive testing to prevent such adverse events is warranted.
**Figure 5.** Example of ECG screening in a patient with cardiac sarcoidosis using Amplia MRI Quad CRT-D with AdaptivCRT Algorithm (Medtronic Inc.). The screening test changed from appropriate (A) to inappropriate (B) along with the change of morphologies of QRS complexes. In both panels, the left ECG shows the 12-lead ECG and the right ECGs show the screening vectors of leads I through III in supine and upright positions.
Surface ECG screening test during pacing therapy compared to that during intrinsic rhythm: Currently, a surface ECG screening test is performed prior to the implantation of S-ICDs to exclude patients who might receive inappropriate shocks. Recently, a high-pass filter was introduced to improve the sensing algorithm. However, the current clinical screening test criteria have not been changed. It is expected that new screening criteria will be introduced in the near future. In this study, we were limited to assessments based on the screening test in current use.

The reported prevalence of the ineligibility for S-ICD implantation in patients without pacing therapy ranges from 7% to 16%. An R/T ratio of less than 3 in the lead with the largest T-wave, T-wave inversion, QRS duration, and low BMI were reported as predictors of failed screening for the S-ICD. Ip et al. reported that the ineligibility for S-ICD implantation in patients who have existing transvenous pacing devices was 42% during ventricular pacing. They included 25 patients with CRT devices, who were less likely to be ineligible compared to those with RV pacing alone (20% versus 54%, P < 0.01). They also showed that patients that were paced from the RV septum were less likely to be ineligible compared to those paced from the apex (33% versus 63%, P < 0.01). Compared to these reports, our study found an ineligibility of 18% during CRT, which was roughly similar to the rate in those without pacing therapy.15,17-19) and those during CRT.20) We could not find a significant relation between the lead positions of CRT and the results of the screening test.

In the previous studies assessing those without pacing therapy, the least favorable sensing vector was the alternate vector.15) On the contrary, the secondary sensing vector was the least favorable during biventricular pacing in our study. We also found that the T/R ratio in lead II, whose vector was similar to the secondary sensing vector, was significantly higher in those who failed the screening test. The difference in the vector of depolarization and repolarization between intrinsic beats and biventricular paced beats might cause this discrepancy. However, there were no significant differences in other electrocardiographic data or lead positions between those that were eligible and those that were ineligible during CRT.

Right parasternal electrode positioning was previously reported to improve the eligibility for S-ICD in patients without pacing therapy.15) This was not the case in our study. There were no patients in whom right parasternal screening test improved eligibility, although 3 out of 8 were not retested in the right parasternum.

T-wave oversensing accounts for the majority of inappropriate shocks in the S-ICD system, ranging from 39% to 73% of all inappropriate shocks.16,21) In our study, during CRT, the main reason for failure was also the high T-wave voltage, although the wide QRS complex also caused ineligibility in 13% of sensing vectors. In this study, we had a few cases in which ECG screening was conducted during both RV and biventricular pacing, or during both RBBB and LBBB pattern QRS complexes, showing varying results. Ip et al. reported that 12 patients who were screened during biventricular pacing were not screened during RV pacing.20) Although we did not screen ECG in multiple pacing modes of CRT in other patients, it is possible that an adjustment in the pacing mode for each patient would increase the number of patients who are eligible, allowing the combination of CRT and S-ICD. In the AdaptivCRT Algorithm, which chooses the most proper pacing mode automatically, the morphologies in all pacing modes should be evaluated during preoperative screening. If there are pacing modes that are ineligible, devices need to be programmed not to switch the pacing mode automatically. For patients who require the 2 devices, adjusting both to prevent exacerbation of heart failure and inappropriate shock delivery is essential. Further study is needed.

Limitations: Our study has several limitations. The major limitation is the small sample size. The underlying heart diseases were also limited, including no congenital heart disease.20) The external validity of our study is limited to the patient population that we studied. Any assessment of eligibility for S-ICD is affected by the population under consideration. The values of subgroup analysis based on the etiology or the lead positions were limited because of the small study population.

As we discussed above, the sensing algorithm in S-ICD technology has been improving. Newer ECG screening methods may improve the rate of eligibility for S-ICD implantation.

When a pacemaker is combined with an S-ICD, the assumption is that both the stimulated and the native heartbeats would be observed, necessitating both morphologies to be evaluated in the ECG screening beforehand. However, we did not assess the native heartbeats in this study because the higher ventricular pacing rate is set as the objective during CRT. We assessed only during the actually used biventricular pacing mode, not during RV pacing.

The preimplant screening assumes that vectors suitable at preimplant screening fulfill criteria for the sensing algorithm of the S-ICD when implanted and exclude patients who fail S-ICD candidacy. The defibrillation ability of S-ICD and the interference between the devices were beyond the scope of this study. The lack of data of the real follow-up and the most appropriate device settings is a limitation of this paper, although we believe that our data about the screening test might help in making decisions for this challenging clinical issue. The follow-up and outcome data need further studies in the future.

We did not study the eligibility for S-ICD in patients with leadless pacemakers.20)

Conclusion

The majority of patients with biventricular pacing were eligible to receive S-ICDs on the basis of currently available screening tests. It may be possible to use an S-ICD together with a CRT-P in such patients, although highly individualized device settings and careful follow-up are necessary. Further study is required.
Disclosures

Conflicts of interest: The authors declare that they have no conflict of interest.

Ethical approval: For this type of study formal consent is not required.

Acknowledgments

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References