Image Quality of Cardiac Magnetic Resonance Imaging in Patients With an Implantable Cardioverter Defibrillator System Designed for the Magnetic Resonance Imaging Environment

Juerg Schwitter, MD; Michael R. Gold, MD, PhD; Ahmed Al Fagih, MD; Sung Lee, MD; Michael Peterson, MD; Allen Ciuffo, MD; Yan Zhang, MS; Nina Kristiansen, PhD; Emanuel Kanal, MD; Torsten Sommer, MD, PhD; on behalf of the Evera-MRI Study Investigators

Background—Recently, magnetic resonance (MR)–conditional implantable cardioverter defibrillator (ICD) systems have become available. However, associated cardiac MR image (MRI) quality is unknown. The goal was to evaluate the image quality performance of various cardiac MR sequences in a multicenter trial of patients implanted with an MR-conditional ICD system.

Methods and Results—The Evera-MRI trial enrolled 275 patients in 42 centers worldwide. There were 263 patients implanted with an Evera-MRI single- or dual-chamber ICD and randomized to controls (n=88) and MRI (n=175), 156 of whom underwent a protocol-required MRI (9–12 weeks post implant). Steady-state-free-precession (SSFP) and fast-gradient-echo (FGE) sequences were acquired in short-axis and horizontal long-axis orientations. Qualitative and quantitative assessment of image quality was performed by using a 7-point scale (grades 1–3: good quality, grades 6–7: nondiagnostic) and measuring ICD- and lead-related artifact size. Good to moderate image quality (grades 1–5) was obtained in 53% and 74% of SSFP and FGE acquisitions, respectively, covering the left ventricle, and in 69% and 84%, respectively, covering the right ventricle. Odds for better image quality were greater for right ventricle versus left ventricle (odds ratio, 1.8; 95% confidence interval, 1.5–2.2; P<0.0001) and greater for FGE versus SSFP (odds ratio, 3.5; 95% confidence interval, 2.5–4.8; P<0.0001). Compared with SSFP, ICD-related artifacts on FGE were smaller (141±65 versus 75±57 mm, respectively; P<0.0001). Lead artifacts were much smaller than ICD artifacts (P<0.0001).

Conclusions—FGE yields good to moderate quality in 74% of left ventricle and 84% of right ventricle acquisitions and performs better than SSFP in patients with an MRI-conditional ICD system. In these patients, cardiac MRI can offer diagnostic information in most cases.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT02117414.

(Circ Cardiovasc Imaging. 2016;9:e004025. DOI: 10.1161/CIRCIMAGING.115.004025.)

Key Words: artifacts ■ heart ventricles ■ Image Quality Enhancement and Cardiac Function Test ■ implantable cardioverter-defibrillator ■ magnetic resonance imaging

Cardiac magnetic resonance imaging (MRI) is generally accepted as a valuable diagnostic tool to detect and monitor a large variety of cardiac diseases; it has both excellent tissue characterization capabilities and high image quality in most cases. In a large population of >9900 patients cardiac image quality was shown to be diagnostic in 98.2%.1 Even in the presence of a pacemaker system, the diagnostic quality of cardiac MRI (CMR) of the left (LV) and right (RV) ventricles is preserved.2 Thus, the high reliability and robustness of CMR is known for patients implanted with a pacemaker system. It is estimated that >60% of patients implanted with an ICD will require an MRI within 10 years post implant,3 and recently an MR-conditional ICD system was shown to be safe and effective when scanned at 1.5 Tesla (T).4 In comparison with pacemakers, the larger size of the ICD pulse generator...
and large defibrillation coil are expected to impact substanti-
ally on image quality. However, to our knowledge, no sys-
tematic prospective study evaluated to date the image quan-
tity generated by different pulse sequences in patients implanted
with an MR-conditional ICD system. Therefore, this study
was performed to assess the image quality obtainable with 2
types of pulse sequences, ie, with steady-state free precession
(SSFP) and fast-gradient-echo (FGE) acquisitions, which are
the most frequently used for CMR. For this purpose, image
quality was graded, image artifacts caused by the ICD and its
leads were measured, and the percentage of examinations with
diagnostic quality was determined for SSFP and FGE acquisi-
tions in the Evera-MRI trial.

Methods

Study Population
The Evera-MRI trial was a multicenter, international, randomized
clinical study confirming the safety and efficacy of patients receiving
a novel ICD system and subjected to an MRI examination.4 The study
enrolled 275 subjects in 42 centers worldwide, of which 263 were
randomized to the MRI (n=175) or control group (n=88) at a 2:1 ratio
after a successful implant. In the MRI group, 156 subjects underwent
a predefined not clinically indicated MRI examination scheduled at
9 to 12 weeks post implant. Of them, 152 subjects had scan data col-
lected for assessing cardiac image quality and therefore are included
in this analysis.

The study protocol was approved by the ethics committee at each
coloring participating institution, and all subjects provided written informed
consent before study participation. The Declaration of Helsinki was
followed as well as laws and regulations of the participating coun-
tries. Trained center personnel collected the data, and its integrity was
maintained by programmatic edit checks and source data verification
by the sponsor.

Study Device
Consented patients received pectoral implantation of an Evera-
MRI single- or dual-chamber ICD (MR-ICD; Medtronic) con-
ected to commercially available defibrillator leads (model 6935M or
6947M) with/without a pacing lead (model 5076) that has been
demonstrated safe for MRI.5 The MR-ICD had specific design and
material modifications to reduce interaction with the MRI environ-
ment as described elsewhere.6 Briefly, ferromagnetic material was
reduced, a hall sensor replaced the mechanical reed switch, filters to
diminished noise and improved ECG triggering, and battery circuitry protection was built in. The Evera-MRI study
prevent gradient and radiofrequency energy coupling were added,
reduced, a hall sensor replaced the mechanical reed switch, filters to
ment as described elsewhere.6 Briefly, ferromagnetic material was
common manufacturers (Siemens, Germany; Philips, Netherlands;
General Electric, USA; and Toshiba, Japan). The MRI protocol was
primarily set up to test for safety of the MRI-conditional ICD system.
To apply the predefined specific absorption rate to all patients, it was
not allowed to repeat sequences or to use contrast media to optimize
image quality. Of the 10 different MRI sequences applied, the 2 clini-
cally relevant cardiac pulse sequences evaluated in this analysis were
cine SSFP and cine FGE acquisitions (Table 1). The SSFP sequence
is nowadays the most commonly used sequence for cardiac functional
analyses. It was used to test whether this sequence is robust enough
to produce adequate quality in the presence of an ICD system. It was
compared with FGE sequences that are known to be less susceptible
to field inhomogeneities. Both sequences were ECG-triggered and were
acquired in short-axis (SA) and horizontal long-axis (HLA) orienta-
tions during breath holding. Before each site’s first patient examination,
a validation of a test MRI scan was performed by an independent Scan
Advisory Board to confirm standardization of the imaging parameters.

Cardiac MRI
The CMR scans were performed on a 1.5T scanner of any of the 4 most
common manufacturers (Siemens, Germany; Philips, Netherlands;
 General Electric, USA; and Toshiba, Japan). The MRI protocol was
primarily set up to test for safety of the MRI-conditional ICD system.
To apply the predefined specific absorption rate to all patients, it was
not allowed to repeat sequences or to use contrast media to optimize
image quality. Of the 10 different MRI sequences applied, the 2 clini-
cally relevant cardiac pulse sequences evaluated in this analysis were
cine SSFP and cine FGE acquisitions (Table 1). The SSFP sequence
is nowadays the most commonly used sequence for cardiac functional
analyses. It was used to test whether this sequence is robust enough
to produce adequate quality in the presence of an ICD system. It was
compared with FGE sequences that are known to be less susceptible
to field inhomogeneities. Both sequences were ECG-triggered and were
acquired in short-axis (SA) and horizontal long-axis (HLA) orienta-
tions during breath holding. Before each site’s first patient examination,
a validation of a test MRI scan was performed by an independent Scan
Advisory Board to confirm standardization of the imaging parameters.

Example Pulse Sequences in an ICD Phantom
An ICD (Evera-MRI XT DR SureScan connected to 6935M and 5076)
was positioned in water at ±5 cm from a heart phantom representing a
SA view of the LV. Standard spin-echo, SSFP, FGE, compressed sens-
ing accelerated SSFP and FGE,7 3-dimensional (3D) self-navigating
SSFP,8 and a silent zero-echo-time sequence9 were applied.

Table 1. Pulse Sequences and Parameters Applied in the Evera-Magnetic Resonance Imaging Trial

<table>
<thead>
<tr>
<th>Sequence Name</th>
<th>FOV, mm</th>
<th>Matrix x</th>
<th>Matrix y</th>
<th>Flip Angle</th>
<th>Breath hold</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cine SSFP: short axis, 3 slices</td>
<td>320–400</td>
<td>168–224</td>
<td>144–224</td>
<td>50–63</td>
<td>Yes (&lt;20 s)</td>
<td>No fat sat, no flow-comp</td>
</tr>
<tr>
<td>Cine FGE: short axis, 3 slices</td>
<td>300–360</td>
<td>192–256</td>
<td>126–180</td>
<td>15–30</td>
<td>Yes (&lt;20 s)</td>
<td>No fat sat</td>
</tr>
<tr>
<td>Cine FGE: horizontal long axis</td>
<td>300–360</td>
<td>192–256</td>
<td>126–160</td>
<td>15–30</td>
<td>Yes (&lt;20 s)</td>
<td>No fat sat</td>
</tr>
</tbody>
</table>

All acquisitions were performed during breath-holding (duration 10–20 s/slice). Slice thickness was 8 to 10 mm for all acquisitions. Repetition time and
echo time were set to minimum for all acquisitions. FGE indicates fast-gradient-echo; FOV, field-of-view; and SSFP, steady-state-free-precession.
Statistical Analysis
For each subject, the images from 2 sequences (SSFP or FGE) in 2 orientations (SA or HLA) and of the 2 ventricles (LV or RV) were evaluated. An ordinal multinomial logistic regression model with generalized estimating equation method was used to analyze the image quality score (grades 1–7) as a correlated ordinal categorical variable, and the effects of sequence type and ventricle type and their interaction on the score were considered. The odds ratios of having a better image quality for different sequences and ventricles were reported using a forest plot. Additional analyses included (1) considering age, sex, and body mass index (BMI) in the above-mentioned model and (2) re-classifying grades into good (grades 1–3), moderate (grades 4–5), and poor (grades 6–7; nondiagnostic) and analyzing this correlated ordinal categorical variable using an ordinal multinomial logistic regression model with generalized estimating equation.

For each subject, the presence and size of lead- or ICD-related artifacts were evaluated for the 2 orientations (SA and HLA) and the 2 sequences (SSFP and FGE). If no artifact was observed, its diameter was given as 0 mm. A general linear mixed model was used to evaluate the effects of artifact type (lead or ICD related), orientation, and pulse sequence and their interactions on the largest diameters of the artifacts. An additional analysis considered age, sex, and BMI using a linear mixed model.

The above-mentioned analyses were based on the assessment of the original reader. In addition, the agreement on image quality scores

Table 2. Image Quality Grading Criteria

<table>
<thead>
<tr>
<th>Rating</th>
<th>Left Ventricle</th>
<th>Right Ventricle</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Regional Function is Well Depicted and Evaluable in n of 13 Segments</td>
<td>Artifacts Interfering With Endo- or Epicardial Borders in n of 13 Segments</td>
<td>Regional Function is Well Depicted and Evaluable in n of 4 Segments</td>
<td>Artifacts Interfering With Endo- or Epicardial Borders in n of 4 Segments</td>
</tr>
<tr>
<td>Good quality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 1</td>
<td>13/13</td>
<td>0</td>
<td>4/4</td>
<td>0</td>
</tr>
<tr>
<td>Grade 2</td>
<td>13/13</td>
<td>≤3</td>
<td>4/4</td>
<td>≤2</td>
</tr>
<tr>
<td>Grade 3</td>
<td>13/13</td>
<td>&gt;3</td>
<td>4/4</td>
<td>&gt;2</td>
</tr>
<tr>
<td>Moderate quality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 4</td>
<td>10–12/13</td>
<td>...</td>
<td>3/4</td>
<td>...</td>
</tr>
<tr>
<td>Grade 5</td>
<td>7–9/13</td>
<td>...</td>
<td>2/4</td>
<td>...</td>
</tr>
<tr>
<td>Poor quality (ie, nondiagnostic)</td>
<td>4–6/13</td>
<td>...</td>
<td>1/4</td>
<td>...</td>
</tr>
<tr>
<td>Grade 6</td>
<td>≤3/13</td>
<td>...</td>
<td>0/4</td>
<td>...</td>
</tr>
</tbody>
</table>

Grading of steady-state free precession and fast-gradient-echo short-axis and long-axis 4-chamber view images.

Figure 1. Representative cardiac images from a study patient implanted with an Evera-Magnetic Resonance Imaging (MRI) implantable cardioverter defibrillator (ICD) system. Four-chamber horizontal long-axis (HLA) and short-axis (SA) acquisitions with the fast-gradient-echo (FGE) and steady-state-free-precession (SSFP) sequences. The FGE images were graded 1 for both ventricles, and the SSFP images were graded 3 and 2 for the left and right ventricle, respectively.
between the original reader and the second reader was estimated using Fleiss $\kappa$ statistics for each sequence by orientation by ventricle combination. The method of Landis and Koch was used to interpret the $\kappa$ values. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC). A $P<0.05$ was considered statistically significant.

**Results**

This study included 152 subjects from the MRI group whose image files for predefined MRI examination were collected (Figure 2). The mean age was 59.7±13.8 years, BMI was 28.9±5.9 kg/m$^2$, 21.7% (33/152) were women, and 11.2% (17/152) of patients were paced during the MRI examination (in 4.0% the pacing status was not known). Of the 152 subjects, 130 had uncorrupted image files that could be assessed, (in 4.0% the pacing status was not known). Of the 152 subjects, 130 had uncorrupted image files that could be assessed, ie, at least 1 pulse sequence type (SSFP or FGE) could be analyzed, and 105, 90, 104, and 77 subjects had assessable data at both SA and HLA orientations for the LV SSFP, LV FGE, RV SSFP, and RV FGE pulse sequence, respectively (Figure 2).

**Image Quality and Type of Pulse Sequences for the LV and RV**

Table 3 presents the quality grading distribution in the study population with higher percentages of diagnostic quality for FGE versus SSFP. FGE yielded good quality in 34.4% and 50.6% for the LV and RV, respectively. If grade 4 or 5 is considered as acceptable quality (1–3 or 4–6 segments not evaluable, respectively), FGE yielded 58.9% and 74.4% successful studies for the LV, respectively, and 67.5% and 84.4% for the RV, respectively. The forest plot of Figure 3 shows higher odds of having a better image quality with the FGE sequence than with the SSFP, regardless of ventricle type (odds ratio, 3.48; 95% confidence interval, 2.52–4.80; $P<0.0001$); and the odds for better image quality was greater for RV versus LV, regardless of pulse sequence type (odds ratio, 1.78; 95% confidence interval, 1.46–2.16; $P<0.0001$). Furthermore, the performances of the pulse sequences were not related to the type of ventricle (no significant interaction between type of pulse sequence and type of ventricle, $P=0.2752$). Men were more likely to present a better image quality than women (odds ratio, 2.63; 95% confidence interval, 1.23–5.63; $P=0.0147$), while age and BMI did not correlate with image quality ($P>0.05$). Re-classifying the quality grades into good (grades 1–3), moderate (grades 4–5), and poor (grades 6–7; ie, nondiagnostic) led to similar results with a greater chance of obtaining better image quality with FGE versus SSFP ($P<0.0001$) and for RV versus LV ($P<0.0001$).

![Flowchart of study participants. Acquisitions were graded if artifacts were related to the implantable cardioverter defibrillator (ICD) system itself (ie, signal void, susceptibility artifacts, image distortion, steady-state-free-precession [SSFP]-related off-resonance banding artifacts, SSFP-related dark flow artifacts). Artifacts not related to the ICD system were not graded including those because of respiratory motion (incorrect breath-holding), ECG-mismatching, incorrect field-of-view (causing wrap-around artifacts), or incorrect image plane orientations. These not graded artifacts are typically corrected in clinical MRI examinations by repeated acquisitions (eventually with individual modifications of scan parameters), which were not allowed in the study to achieve predefined specific absorption rate exposition in all patients. *Percentage calculated using $n=152$ as the denominator. FGE indicates fast-gradient-echo; HLA, horizontal long-axis; LV, left ventricle; and RV, right ventricle.](http://circimaging.ahajournals.org/)

**Figure 2.** Flowchart of study participants. Acquisitions were graded if artifacts were related to the implantable cardioverter defibrillator (ICD) system itself (ie, signal void, susceptibility artifacts, image distortion, steady-state-free-precession [SSFP]-related off-resonance banding artifacts, SSFP-related dark flow artifacts). Artifacts not related to the ICD system were not graded including those because of respiratory motion (incorrect breath-holding), ECG-mismatching, incorrect field-of-view (causing wrap-around artifacts), or incorrect image plane orientations. These not graded artifacts are typically corrected in clinical MRI examinations by repeated acquisitions (eventually with individual modifications of scan parameters), which were not allowed in the study to achieve predefined specific absorption rate exposition in all patients. *Percentage calculated using $n=152$ as the denominator. FGE indicates fast-gradient-echo; HLA, horizontal long-axis; LV, left ventricle; and RV, right ventricle.
Table 3. Image Quality: Influence of Pulse Sequence Type

<table>
<thead>
<tr>
<th>Rating</th>
<th>Left Ventricle</th>
<th>Right Ventricle</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SSFP Cine</td>
<td>FGE Cine</td>
</tr>
<tr>
<td></td>
<td>Sequences</td>
<td>Sequences</td>
</tr>
<tr>
<td>Not graded</td>
<td>25</td>
<td>40</td>
</tr>
<tr>
<td>Graded (=100%)</td>
<td>105</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>104</td>
<td>77</td>
</tr>
<tr>
<td>Good IQ (grade 1–3), n (%)</td>
<td>11 (10.5)</td>
<td>31 (34.4)</td>
</tr>
<tr>
<td></td>
<td>16 (15.4)</td>
<td>39 (50.6)</td>
</tr>
<tr>
<td>Image quality grade 1</td>
<td>1 (1.0)</td>
<td>4 (4.4)</td>
</tr>
<tr>
<td></td>
<td>1 (1.0)</td>
<td>4 (5.2)</td>
</tr>
<tr>
<td>Image quality grade 2</td>
<td>4 (3.8)</td>
<td>17 (18.9)</td>
</tr>
<tr>
<td></td>
<td>9 (8.7)</td>
<td>16 (20.8)</td>
</tr>
<tr>
<td>Image quality grade 3</td>
<td>6 (5.7)</td>
<td>10 (11.1)</td>
</tr>
<tr>
<td></td>
<td>6 (5.8)</td>
<td>19 (24.7)</td>
</tr>
<tr>
<td>Moderate IQ (grade 4–5), n (%)</td>
<td>45 (42.9)</td>
<td>36 (40.0)</td>
</tr>
<tr>
<td></td>
<td>56 (53.8)</td>
<td>26 (33.8)</td>
</tr>
<tr>
<td>Image quality grade 4</td>
<td>10 (9.5)</td>
<td>22 (24.4)</td>
</tr>
<tr>
<td></td>
<td>27 (26.0)</td>
<td>13 (16.9)</td>
</tr>
<tr>
<td>Image quality grade 5</td>
<td>35 (33.3)</td>
<td>14 (15.6)</td>
</tr>
<tr>
<td></td>
<td>29 (27.9)</td>
<td>13 (16.9)</td>
</tr>
<tr>
<td>Poor IQ (grade 6–7; nondiagnostic), n (%)</td>
<td>49 (46.7)</td>
<td>23 (25.6)</td>
</tr>
<tr>
<td></td>
<td>32 (30.8)</td>
<td>12 (15.6)</td>
</tr>
<tr>
<td>Image quality grade 6</td>
<td>21 (20.0)</td>
<td>9 (10.0)</td>
</tr>
<tr>
<td></td>
<td>14 (13.5)</td>
<td>4 (5.2)</td>
</tr>
<tr>
<td>Image quality grade 7</td>
<td>28 (26.7)</td>
<td>14 (15.6)</td>
</tr>
<tr>
<td></td>
<td>18 (17.3)</td>
<td>8 (10.4)</td>
</tr>
<tr>
<td>Image file corrupted</td>
<td>3 (0.5)</td>
<td>3 (0.6)</td>
</tr>
</tbody>
</table>

FGE indicates fast-gradient-echo; IQ, image quality; and SSFP, steady-state-free-precession.

*Better quality was more likely for the FGE sequence than for the SSFP sequence (P<0.0001) and for the right ventricle than for the left ventricle (P<0.0001).

As shown in Table 4, for the 2 readers, substantial to almost perfect agreement (κ=0.6–0.8) was observed for almost all acquisition types. Only for 2 acquisitions (FGE of the LV and SSFP of the RV) at the moderate quality level, the agreement was moderate (κ=0.4–0.6).

Size of Artifacts of the ICD and the Leads and Type of Pulse Sequences

Lead- and ICD-related artifacts were observed among most of the subjects, except for the FGE sequence in the HLA plane for which no ICD-related artifacts were present in 49.5% of patients (Table 5).

The analysis of artifact size and type (ie, ICD related and lead related) based on a general linear mixed model showed significant interaction effects for artifact type with pulse sequence and for artifact type with slice orientation. Specifically, ICD-related artifacts on the FGE sequence were smaller than those on the SSFP sequence (Figure 4A; 75.0±56.7 versus 140.9±65.2 mm; P<0.0001). Also, ICD-related artifacts on the HLA orientation were smaller than those on the SA orientation (Figure 4B; 78.8±69.6 versus 139.4±54.6 mm; P<0.0001). Lead-related artifacts were smaller than ICD-related artifacts irrespective of the pulse sequence type (Figure 4A; P<0.0001) or orientation of acquisition (Figure 4B; P<0.0001). The difference in the lead-related artifact diameters between the FGE and the SSFP sequence was small from a clinical point of view, but it was statistically significant (Figure 4A; 10.2±3.2 versus 8.3±3.3 mm; P<0.0001). The difference in lead-related artifact diameters between HLA and SA orientations was even smaller (Figure 4B; 8.7±3.7 versus 9.8±2.9 mm; P<0.0001). Age, sex, and BMI were not associated with artifact size (P>0.05).

Examples of Pulse Sequences Not Used in the Clinical Trial

In the phantom example in Figure 5, 2D-SSFP–based (Figure 5B) and 3D-SSFP–based (Figure 5D) sequences show substantially larger artifacts than the FGE-based sequences (Figure 5C and 5G). A novel 3D-zero-echo-time sequence (Figure 5H) sequence shows small ICD-related artifacts in comparison with the SSFP and FGE sequences used in the trial. In a
Discussion
This study is the first evaluating in a large multicenter setting the diagnostic performance of SSFP- and FGE-based pulse sequences in patients implanted with an MR-conditional ICD system. It demonstrates that good to moderate image quality is obtainable with FGE in 74% of LV and 84% of RV acquisitions and it yields substantially higher image quality than SSFP acquisitions. Moreover, the ICD generator is the relevant system component that can potentially degrade image quality, and this is dependent on the pulse sequence type, while the leads are of minor importance with regard to artifacts.

Quality of CMR Images: Influence of Pulse Sequence Type and Orientation of Acquisition
In a single-center study, Sasaki et al. found diagnostic quality with SSFP in 85.5% of cases (by using the criterion of more than half of LV segments being distorted to define non-diagnostic image quality as in the current study), whereas the SSFP sequence in the present study yielded diagnostic quality in only 53% and 69% of the RV and LV, respectively. This considerably lower performance of the SSFP sequence in the current study may be, in part, because of the inclusion of 42 centers, whereas the study of Sasaki et al. included 56 scans in a single center. Nevertheless, when using the SSFP cine sequence, the single-center study reported a mean artifact diameter for the ICD device on SA images of 16.0 cm, which is comparable with the size found in the current study of 16.7 cm (Table 5). In another small cohort of patients with metal implants of various origin, a better image quality of CMR was found for FGE acquisitions in comparison with SSFP. These findings and the results of the current study are in agreement with the fact that the SSFP sequence is more susceptible to field inhomogeneities than the FGE sequence. Importantly, many pulse sequences used in clinical MRI practice for viability/scar imaging, myocardial perfusion imaging, tagging, and flow measurements are using FGE-type readouts. Also, highly accelerated cardiac acquisitions based on novel compressed sensing strategies can use the FGE read-out scheme, and thus are expected to work reliably in patients with this implanted ICD system as shown in the example in Figures 5 and 6.

Table 4. Agreement Between 2 Readers: κ Statistics

<table>
<thead>
<tr>
<th>Rating</th>
<th>κ Statistics</th>
<th>Left Ventricle</th>
<th>Right Ventricle</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>SSFP Cine Sequences</td>
<td>FGE Cine Sequences</td>
</tr>
<tr>
<td>Could not be graded</td>
<td>0.81</td>
<td>0.74</td>
<td>0.80</td>
</tr>
<tr>
<td>Good IQ (grade 1–3)</td>
<td>0.83</td>
<td>0.70</td>
<td>0.76</td>
</tr>
<tr>
<td>Moderate IQ (grade 4–5)</td>
<td>0.70</td>
<td>0.50</td>
<td>0.56</td>
</tr>
<tr>
<td>Poor IQ (grade 6–7)</td>
<td>0.75</td>
<td>0.80</td>
<td>0.70</td>
</tr>
<tr>
<td>Overall (n=130)</td>
<td>0.76</td>
<td>0.69</td>
<td>0.68</td>
</tr>
</tbody>
</table>

Degree of agreement: κ≤0: poor; >0 to 0.2: slight; >0.2 to 0.4: fair; >0.4 to 0.6: moderate; >0.6 to 0.8: substantial; >0.80: almost perfect. FGE indicates fast-gradient-echo; IQ, image quality; and SSFP, steady-state-free-precession.

Table 5. Presence and Size of Artifacts

<table>
<thead>
<tr>
<th></th>
<th>Lead Related</th>
<th>ICD Related</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SSFP SA</td>
<td>SSFP HLA</td>
</tr>
<tr>
<td>Analyzed</td>
<td>118</td>
<td>114</td>
</tr>
<tr>
<td>Artifact not present, n (%)</td>
<td>0 (0)</td>
<td>9 (7.9)</td>
</tr>
<tr>
<td>Artifact present, n (%)</td>
<td>118 (100)</td>
<td>105 (92.1)</td>
</tr>
<tr>
<td>Mean±SD, mm</td>
<td>9.1±3.2</td>
<td>7.6±3.3</td>
</tr>
<tr>
<td>Median, mm</td>
<td>8.0</td>
<td>7.0</td>
</tr>
<tr>
<td>Min–max, mm</td>
<td>5.0–25.0</td>
<td>0.0–20.0</td>
</tr>
<tr>
<td>Could not be analyzed*</td>
<td>12</td>
<td>16</td>
</tr>
</tbody>
</table>

*Images with incorrect acquisition of standard cardiac planes, severe wrap-around artifacts obscuring parts of the left or right (RV) ventricles or severe image blurring caused by poor breath-holding or poor ECG-triggering were considered nonanalyzable. FGE indicates fast-gradient-echo; HLA, horizontal long-axis; ICD, implantable cardioverter defibrillator; SA, short-axis; and SSFP, steady-state-free-precession.
The diagnostic performance in the patients with an MR-conditional ICD system of 53% and 69% for the LV and RV, respectively, reported in this study is also considerably lower than that observed for an MR-conditional pacemaker evaluated in a multicenter trial and ranging from 95% of diagnostic studies for the LV to 98% for the RV. This difference is most likely explained by the amount of ferromagnetic materials contained in the ICD.

It is noteworthy that no contrast media was applied (in order not to confound the safety analysis of the study). It might be recommended to improve the diagnostic performance of FGE by administering contrast media to increase the endocardial border delineation on FGE-based images, particularly for long-axis acquisitions.

Based on this large trial performed at 42 centers, the FGE is the pulse sequence of choice for patients with an implanted ICD system and the HLA acquisition yielded even higher quality than SA acquisitions.

Image Artifacts: Influence of ICD System Components

The study clearly identifies the ICD generator as the relevant component of the ICD system to cause imaging artifacts. The fact that the ICD is the limiting factor on artifacts also explains why image quality was higher for the RV than for the LV, as the ICD is located closer to the LV than the RV as shown in Figures 1 and 6. Consequently, in ICD patients who have insufficient echocardiographic quality, it seems reasonable to undergo a CMR, especially, if RV pathologies are suspected. Although the leads are particularly important with regard to side effects such as heating, they are not contributing much to image artifacts, and thus, they are generally not compromising image quality. This is in agreement with a recent study on image quality of MR-conditional pacemakers, where a high diagnostic quality was documented.

The spectrum of artifacts observed in the current study can be divided into those related to patients’ collaboration and
anatomy (inadequate breath-holding, wrap-around artifacts, ECG-mistiggering) and those related to the device, ie, the ICD generator (susceptibility artifacts, signal voids, SSFP-related off-resonance banding artifacts, and SSFP-related dark flow artifacts). It is highly desirable to develop and design new pulse sequences that are dedicated to image the heart in the presence of ICD systems, ie, with optimal robustness against field distortions. New pulse sequences are available to image with less artifacts near metallic implants.21 However, these novel sequences are often spin-echo–based and as such they...
are not time efficient and not well suited to provide functional information of the heart. As shown in the phantom example in Figure 5, alternative types of pulse sequences that collect data during the free induction decay of the signal after excitation, the so-called ultrashort or zero-echo-time techniques show the potential for a robust acquisition in inhomogeneous magnetic fields.\textsuperscript{23} They could present a novel approach to yield functional images of the heart in the presence of devices.\textsuperscript{23} Also novel shimming procedures could reduce the occurrence of such device-related artifacts. Future research on novel dedicated pulse sequences and shimming procedures are needed and with the advent of MRI-conditional ICDs such approaches can now be tested in patients.

**Limitations**

This study should be interpreted in light of certain limitations. The higher robustness of the FGE sequence in comparison with SSFP comes at the cost of reduced signal-to-noise in the blood pool, and thus, discrimination of the blood–myocardium interface is typically lower than with SSFP-type pulse sequences.\textsuperscript{24} Accordingly, administration of contrast media would be of value in patients with implantable cardiac defibrillators. Dr Kanal is a consultant to Medtronic, Boston Scientific, and St. Jude Medical. Drs Peterson, Lee, and Fagih are study Investigators. Y. Zhang and Dr Kristiansen are employees of Medtronic.

**Conclusions**

FGE produces better quality and smaller ICD-related artifacts for CMR than SSFP in patients with an MRI-conditional ICD system. FGE yields good to moderate image quality in this multicenter setting in 74\% of LV and 84\% of RV acquisitions. In these patients implanted with ICD systems designed for the CMR environment, CMR can offer diagnostic information in most cases.

**Acknowledgments**

We are grateful to Jean Delacoste, MSc, Department of Radiology, University Hospital Lausanne, Switzerland, for performing the phantom acquisitions.

**Sources of Funding**

The Evera-MRI Study was sponsored by Medtronic, Minneapolis, MN.

**Disclosures**

Dr Gold is a consultant to and receives clinical trials funds from Medtronic, Boston Scientific, and St. Jude Medical. Dr Kanal is a consultant to Medtronic, Boston Scientific, and St. Jude Medical. Dr Ciuffo is a consultant to Medtronic and Boston Scientific. Drs Schwitter and Dr Sommer are consultants to Medtronic. Drs Peterson, Lee, and Fagih are study Investigators. Y. Zhang and Dr Kristiansen are employees of Medtronic.

**References**


**CLINICAL PERSPECTIVE**

Magnetic resonance imaging (MRI) of the heart is increasing in importance, particularly for the evaluation of heart failure and coronary artery disease. MRI-conditional pacemakers and, more recently, implantable cardioverter defibrillator (ICD) systems, are available. Imaging at sites remote from the pacemaker/ICD is rarely a problem. However, little is known about cardiac imaging. This is of particular concern for ICDs given the large pulse generator and more complex leads, including metallic coils. The Evera-MRI trial included 175 patients who were randomized to undergo a protocol-required MRI at 9 to 12 weeks post implant. Steady-state-free-precession and fast-gradient-echo sequences were acquired, and image quality was assessed qualitatively and quantitatively (ICD- and lead-related artifact size). Good to moderate image quality was obtained in 74% and 84% of fast-gradient-echo acquisitions covering the left and right ventricle, respectively. ICD-related artifacts were much larger than lead artifacts on both steady-state-free-precession and fast-gradient-echo. These results indicate that fast-gradient-echo is currently the pulse sequence of choice in ICD-implanted patients, yielding good to moderate quality in the majority of examinations. Nevertheless, these results also indicate that there is a need for further development of pulse sequences and novel shimming procedures dedicated to minimize ICD-related artifacts. With the advent of MRI-conditional ICDs, new strategies can now be tested in ICD-implanted patients.
Image Quality of Cardiac Magnetic Resonance Imaging in Patients With an Implantable Cardioverter Defibrillator System Designed for the Magnetic Resonance Imaging Environment

Juerg Schwitter, Michael R. Gold, Ahmed Al Fagih, Sung Lee, Michael Peterson, Allen Ciuffo, Yan Zhang, Nina Kristiansen, Emanuel Kanal and Torsten Sommer

on behalf of the Evera-MRI Study Investigators

_Circ Cardiovasc Imaging_. 2016;9:
doi: 10.1161/CIRCIMAGING.115.004025

_Circulation: Cardiovascular Imaging_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2016 American Heart Association, Inc. All rights reserved.
Print ISSN: 1941-9651. Online ISSN: 1942-0080

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circimaging.ahajournals.org/content/9/5/e004025

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in _Circulation: Cardiovascular Imaging_ can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to _Circulation: Cardiovascular Imaging_ is online at:
http://circimaging.ahajournals.org/subscriptions/