Clinical MRI Examination of Patients with Implantable Cardiac Devices
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Background

- Performing MRI on patients with cardiac implantable electronic devices (CIEDs) has become more accepted in recent years due to increasing evidence of safety with these devices.

- Our institution created a multidisciplinary team of radiologists, cardiologists, radiology technologists, radiology nurses, electrophysiology (EP) nurses, and hospital administrators to produce a protocol for screening and completion of MRIs in patients with CIEDs.

- The initial version of the protocol drew on current literature and was adapted throughout its implementation to reflect the most up-to-date recommendations, including the 2017 Heart Rhythm Society Guidelines.

- The purpose of this study was to evaluate the safety of this protocol over the first 2.5 years of implementation.
Methods: Patient population and Demographics

• The University of North Carolina institutional review board approved this retrospective HIPAA-compliant study with a waiver of written informed patient consent.

• Inclusion criteria for the study included:
  • Patients over the age of 18
  • Patients with a current cardiac implantable device
  • A physician order for an MRI between June 1, 2016 and December 1, 2018

• A total of 238 patients between the ages of 25-93 were included in the study, with an average age of 66.1 years. 62% of the patients were male, 38% female.
Methods: Protocol Development and Implementation

• A multidisciplinary team of radiologists, cardiologists, radiology technologists, radiology nurses, electrophysiology (EP) nurses, and hospital administrators formulated an MRI safety protocol and a site-specific process flowchart for patients with both MR-conditional and MR-nonconditional CIEDs.

• This protocol was dynamic in that it was updated multiple times during its implementation to reflect the most current literature.

• The aim of the protocol was to expedite the completion of MRIs for patients with implantable cardiac devices, both MRI-conditional and MRI-nonconditional devices.

• An overview of the protocol will be provided in the following slides.
Methods: Pre-Scan Screening Protocol

- First, an order is placed for the MRI and the MRI supervisor determines if the patient has a CIED.
- The ordering provider provides a referring provider letter (RPL) which states the medical necessity for the test.
- The electrophysiology nurse performs a remote assessment of the patient’s history to determine if the patient has any contraindications to MRI\(^1\)
- If MRI is not contraindicated, the EP nurse will determine if the patient needs physician evaluation prior to MRI\(^2\).
- Once approved by cardiology for the MRI, the MRI is scheduled.

\(^1\) Contraindications to MRI include patients with fractured CIED leads, epicardial leads, multiple CIED manufacturer implants, or if the patient is pacemaker-dependent with an MRI-nonconditional CIED.

\(^2\) Indications for physician evaluation included greater than 6 months since last in-person or remote electrophysiology evaluation for a patient with an MRI-nonconditional device. Not required for patients with MR-conditional devices.
Methods: Scanning Protocol

• Once the patient arrives for their MRI, the following protocol is followed:

1 If on post-scan interrogation, the CIED capture threshold is increased by greater than 1.0 volts, a sensing voltage drop of greater than 50%, a pacing impedance change of greater than 50 ohms, or a shock impedance change greater than 5 ohms, the patient will be seen by cardiology within 2 weeks of the scan.
Methods: Data Collection

• Retrospective chart review of patients screened for MRI after initiation of the above protocol between June 1, 2016 and December 1, 2018 was undertaken.

• Data obtained
  • Age
  • Gender
  • Pacemaker Dependency Status
  • MRI Date
  • Body part scanned
  • Exam limitations as reported by radiologist or radiology technologist
  • Presence of artifact from pacemaker
  • Adverse events: death or cardiac arrhythmia during or immediately after scan
  • Device Complications: CIED capture threshold increase greater than 1.0 volts, sensing voltage drop greater than 50%, pacing impedance change greater than 50 ohms, or shock impedance change greater than 5 ohms.
Results

A total of 237 patients were screened for MRI under the CIED MRI protocol between June 1, 2016 and December 1, 2018. Of the 237 patients screened, 197 (83.1%) underwent MRI. A total of 256 separate MRI exams were performed.

40 patients did not undergo MRI (i.e. no-show or death) or were found to be contraindicated for MRI as outlined below.

<table>
<thead>
<tr>
<th>Contraindication for MRI</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemaker-dependent with MRI-nonconditional CIED</td>
<td>11</td>
</tr>
<tr>
<td>Abandoned CIED leads</td>
<td>4</td>
</tr>
<tr>
<td>Epicardial Leads</td>
<td>3</td>
</tr>
<tr>
<td>Multiple pacemaker implant manufacturers</td>
<td>1</td>
</tr>
</tbody>
</table>
Results

• Of the 197 patients who underwent MRI,
  • 78 (39.6%) had MRI-nonconditional devices
  • 119 (60.4%) had MRI-conditional devices
    • Of the 119 patients with MRI-conditional devices, 27.7% were pacemaker dependent.
    • No MRI-nonconditional device patients were pacemaker dependent

• Of the 256 MRIs completed,
  • ZERO ADVERSE EVENTS
    • One device complication: pacemaker had a sensing voltage drop of 50% on post-MRI interrogation. Patient’s pacemaker was reset to original settings following the MRI, and the patient was seen in clinic within 2 weeks without complication.
  • MRI characteristics as described in the provided table:

<table>
<thead>
<tr>
<th>MRI Characteristics</th>
<th>Number of Scans (percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total MRIs</td>
<td>256 (100.0)</td>
</tr>
<tr>
<td>Outpatient</td>
<td>176 (68.8)</td>
</tr>
<tr>
<td>Inpatient</td>
<td>80 (31.2)</td>
</tr>
<tr>
<td>Abdomen and/or pelvis</td>
<td>46 (18.0)</td>
</tr>
<tr>
<td>Brain</td>
<td>127 (49.6)</td>
</tr>
<tr>
<td>Spine</td>
<td>47 (18.4)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>10 (3.9)</td>
</tr>
<tr>
<td>Extremity</td>
<td>26 (10.1)</td>
</tr>
</tbody>
</table>
Discussion

• Implementation of a site-specific protocol for screening and performing MRI on patients with both MRI-conditional and MRI-nonconditional CIEDs led to completion of 256 MRIs on 197 patients with no adverse events (death or cardiac arrhythmia).

• To our knowledge, this is the largest single-center study aimed at assessing MRI safety for patients with CIEDs.

• Our data is in agreement with numerous other studies which illustrated minimal risk for appropriately screened patients.

• Implementation of this protocol allowed for a multidisciplinary approach that maximizes completion of MRI safely in patients with CIEDs. No physician is required to be present for the scan, making this largely a nurse- and technologist-driven protocol.
Discussion

Limitations

• Retrospective design

Recent protocol update

• Since completion of this study, our institution has removed the requirement for a Referring Physician Letter for patients with MRI-conditional devices as these devices are FDA-approved for MRI and this step was found to delay MRI completion.
Conclusion

• Patients with CIEDs are able to safely undergo MRI without adverse events using this imaging protocol.

• Pre-Scan Screening Protocol

  MRI Ordered → Referring Provider Letter Received → Electrophysiology nurse screening consult → Cleared for MRI by EP RN or Cardiology MD → Proceed to MRI

• Scanning protocol

  Patient arrives for MRI → Confirm RPL and EP/cardiology consult performed on patient → Alert radiology RN and EP RN of patient arrival → Pre-MRI device interrogation by EP RN → Perform MRI with continuous monitoring by radiology RN and ICU RN if patient is in critical care unit → On completion of scan, repeat device interrogation by EP RN → Patient discharged home if device parameters within normal limits, or if device parameters not within normal limits, patient will be seen by cardiology MD
Irnich W. Risks to pacemaker patients undergoing magnetic resonance imaging examinations. Europace 2010;12(7):918–920.


Coman IA, Martin ET, Sandler DA, Thomas JR. Implantable cardiac defibrillator interactions with magnetic resonance imaging at 1.5 Tesla. J Am Coll Cardiol 2004;43:138A.


