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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

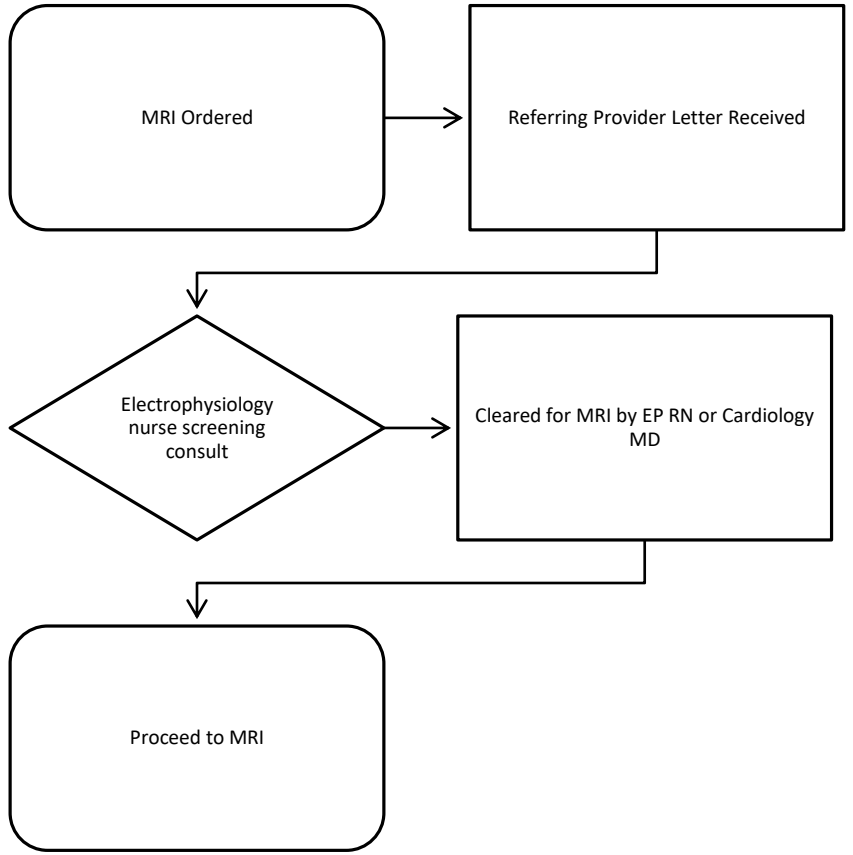
- The University of North Carolina institutional review board approved this retrospective HIPAA-compliant study with a waiver of written informed patient consent.
- Inclusion criteria for the study included:
  - Patients over the age of 18
  - Patients with a current cardiac implantable device
  - A 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.

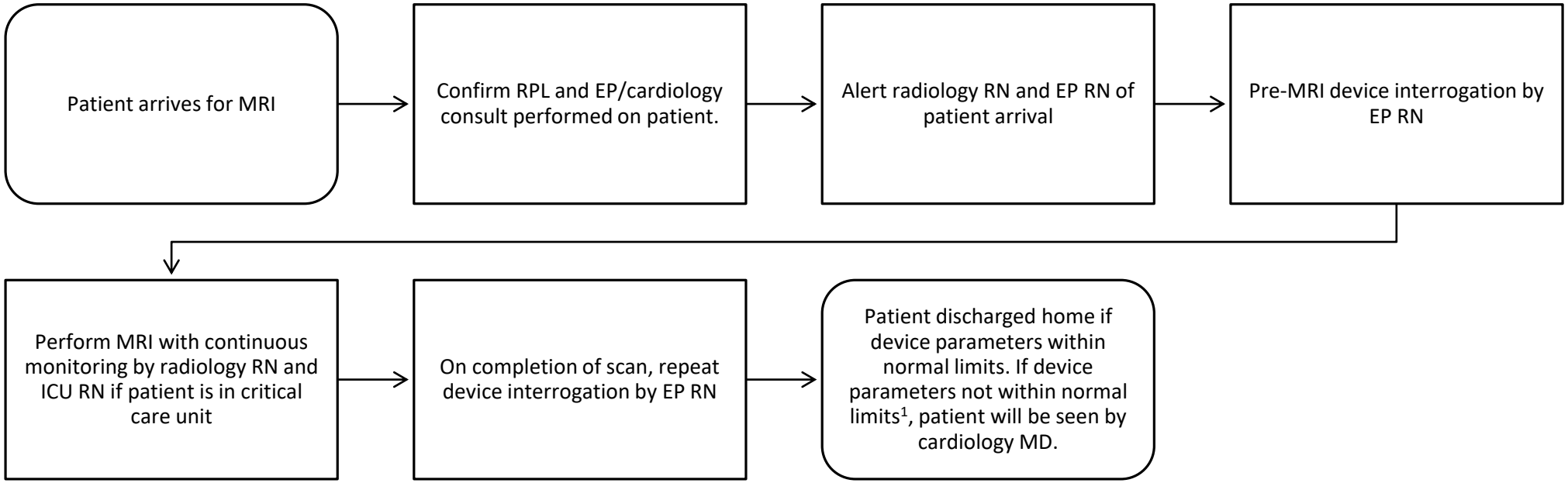


[1] Contraindications to MRI include patients with fractured CIED leads, epicardial leads, multiple CIED manufacturer implants, or if the patient is pacemaker-dependent with an MRI-nonconditional CIED.

[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.

Contraindication for MRI	Number of Patients
Pacemaker-dependent with MRI-nonconditional CIED	11
Abandoned CIED leads	4
Epicardial Leads	3
Multiple pacemaker implant manufacturers	1

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:

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

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

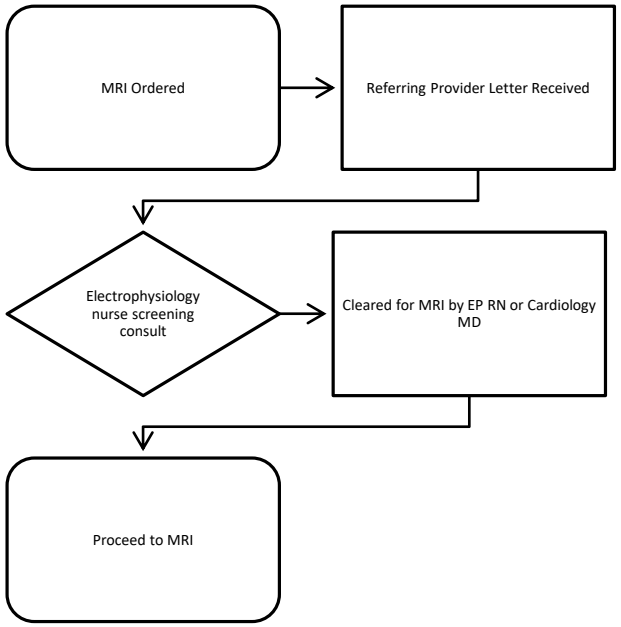
Recent protocol update

- 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.

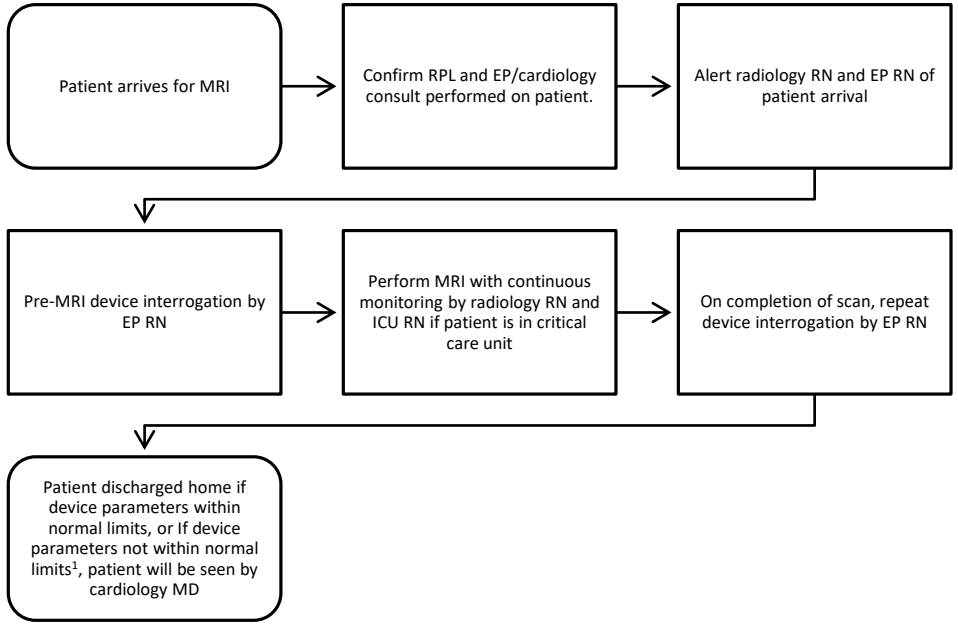
Conclusion

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

- Pre-Scan Screening Protocol



- Scanning protocol



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