Evaluating MRI Scanning in Patients with Fractured or Abandoned Endocardial Leads

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Background

Millions of people in the United States and around the world have an implanted cardiac device. Between 1993 and 2009, overall pacemaker use increased by 50%, with 2.9 million permanent pacemakers implanted (Ferreira, et al, 2014). As of 2003, an estimated three million people met implant criteria for an implantable cardiac defibrillator (ICD) for either primary or secondary prevention (Nazarian, et al, 2006).

It is further estimated that up to 75% of patients with a pacemaker or ICD will need medical magnetic resonance imaging (MRI) at some point following device implant (Nazarian, et al, 2006). Patients over 65 years of age comprise the majority of patients with implanted pacemakers or ICDs, and thus are extremely likely to require a MRI at some point after device implant.

MRIs provide excellent spatial resolution and multi-plane 3-D analysis. MRI is particularly good for soft tissue imaging and is the preferred imaging method for many neurological and musculoskeletal conditions (Mollerus, Albin, Lipinski, & Lucca, 2008). In addition to its superior imaging characteristics, MRI does not expose patients to ionizing radiation.

Pacemakers and ICDs have long been considered an absolute contraindication MRI due to concerns of the potential interactions between MRI and implantable cardiac devices including:

- Tissue heating, especially at the lead tip/myocardial interface
- Induction of ventricular arrhythmias such as ventricular tachycardia/fibrillation
- Pacemaker reset
- Reed switch closure, resulting in suspension of tachyarrhythmia detection/therapies
- Inhibition of pacing
- Increased pacing threshold/failure to capture
- Damage to circuitry

In recent years, however, several studies have concluded that MRI can be safe for patients with non-MRI conditional pacemakers and/or ICDs (Nazarian, et al, 2006, 2011, 2017). In 2011, Nazarian et al. published the results of their study of patients with pacemakers (237) or ICDs (201) who underwent medically indicated MRI. The study indicated that MRI is safe for pacemaker and ICD patients when appropriate screening protocols are in place and followed, with no immediate or

long-term events requiring lead or system revision or reprogramming (Nazarian, et al., 2011). A 2008 study determined that MRI scanning did not cause sufficient damage to the myocardium to produce a significant rise in troponin-I levels (Mollerus, Albin, Lipinski, & Lucca, 2008). In 2009, Mollerus et al also determined that device patients undergoing MRI did not have any increase in arrhythmic activity during the scan (Molerus, Albin, Lipinski, & Lucca, 2009).

Previous MagnaSafe, Johns Hopkins, and Lancaster General Health (LGH) studies have shown that non-MRI-conditional cardiac implanted electronic device (CIED) patients without fractured or abandoned leads can safely be scanned with an MRI. The previous studies showed that accessibility to MRI allowed for diagnostic benefits in these patients that might not have been available with other imaging modalities. As a result of these studies, CMS changed restrictions for non-MRI conditional CIEDs in 2018. However, due to safety concerns and sparse data in the patient population with fractured or abandoned leads, these patients remain excluded from the current CMS coverage determination. These continued restrictions on MRI availability for patients with non-functional leads prevents accessibility to this important imaging technology and its potential impact on clinical management. In addition, physicians may alter management of these patients to avoid abandoning leads, often by choosing potentially dangerous lead extraction procedures, simply to allow for future MRIs.

Data from the Mayo Clinic in which 90 MRI scans were performed on 80 patients with fractured or abandoned leads demonstrated no clinical adverse events, and no biochemical evidence of myocardial damage (Padmanabhan et al., 2017). The Hospital of the University of Pennsylvania similarly conducted 34 MRI scans on patients with fractured or abandoned leads, resulting in no clinical adverse events (Brunket at al., 2001). These studies suggest that MRI can be performed in this population with low risk and with the potential for significant clinical benefit. However, in addition to excluding these patients from its coverage determination, CMS also removed the option for centers to be reimbursed for such MRIs if conducted in research studies, thereby increasing the cost of any further research and decreasing its likelihood.

A recent editorial in JAMA Cardiology (Kramer et al., 2018) decries the restrictions in the CMS coverage determination and concludes that a large multi-center study should be conducted. The study aims to collect data to demonstrate the safety of MRI.

Objectives

The primary aim of this study is to determine if MRIs can be safely performed in patients with abandoned or fractured leads.
The secondary aim of this study is to assess the impact of MRI availability by surveying ordering physicians about the impact of MRI availability on patient care, in the population of patients excluded from current CMS reimbursement for MRI due to device lead characteristics.

The purpose of this study is to determine the safety and efficacy of MRI scanning in patients with fractured or abandoned endocardial leads. Specifically, the investigators aim to provide community-acquired data that can be used in Medicare and Medicaid coverage determinations and to investigate whether patients with fractured or abandoned leads can safely be scanned using an MRI and to evaluate the impact of MRI availability on patient care in this population. This study also aims to validate similar studies conducted by Mayo Clinic, the Hospital of the University of

Pennsylvania and Johns Hopkins Medicine that employ MRI in the abandoned lead patient population.

Methods

This study is a prospective descriptive single-site study that will take place at Lancaster General Hospital.

Inclusion**:**

- Patients implanted with an ICD or pacemaker with an abandoned or non-functional endocardial lead, and who have a clinical need for MR imaging
- Patients are English or Spanish speaking and able to review and sign the consent

Exclusion**:**

- Patients who meet current CMS approved indications for MRI with cardiac implanted electronic device
- Patients who complete the MRI standard screening form and are deemed inappropriate for MRI for any reason other than abandoned or fractured endocardial, or epicardial lead.
- Patients less than 18 years of age

Any patients with fractured or abandoned endocardial leads with or without a pacemaker or ICD implanted after 2001 who meet the all of the inclusion and none of the exclusion criteria and who require a medically indicated MRI will be eligible to enroll in the study. MRI scans will be performed utilizing institutional protocols and appropriate settings for the patient population. The EP physician/Advanced Practice Provider will monitor participant heart rhythms and symptoms during, before, and after the MRI scan. The ordering physician will be surveyed to assess how the availability of MRI impacted patient care. We propose to screen 60 but enroll 30 participants at the site over a period of 2 years.

All studies will be done in the existing MRI units at the MRI Group. MRI scan sequences, field intensity and fields of exposure will be given no special consideration given the presence of the pacemaker or ICD. ECG monitoring pads will be placed on the participants for the duration of the study. An external defibrillator and ACLS drugs will be on hand. Heart rate, heart rhythm, blood pressure, O2 saturation will also be monitored non-invasively throughout the study by a doctor, registered nurse, or technician trained in devices and ACLS. Symptoms will be assessed during and after completion of the MRI.

All devices will undergo a complete interrogation and testing prior to imaging and following imaging. Parameters such as atrial and ventricular pacing thresholds, R and P wave amplitudes, lead impedance, and battery status will be measured and recorded. PPMs will be programmed to an asynchronous mode if dependent and to an inhibited mode in participants without pacemaker dependence, as per current protocols for MRI with cardiac implanted electronic devices.

After the appropriate MRI protocol for each MRI participant is completed, the device will be re-programmed to its original settings and completely interrogated and retested to detect any changes in device performance.

All MRI's are clinically indicated and therefore standard of care. The participants' participation in the study will terminate when they complete the MRI and device check.

Participants or their insurance companies will be responsible for the cost of the MRI.

Participant information that will be collected includes name, medical record number, name of ordering physician, device data and any symptoms experienced during MRI.

Data Collection and Management

Data collection is under the supervision of the PI. Data will be managed by the Research Institute. All study relevant data will be entered into REDCap (Harris, 2009), a 21 CFR Part 11-compliant data capture system provided and maintained by the Research Institute.

Data Monitoring Safety Plan

The Data Safety Monitoring Board (DSMB) for this Registry will be comprised of three individuals who work at LGH, and will include a statistician, a radiologist specializing in MRI procedures, and an EP cardiologist or other technical staff familiar with cardiac device parameters and programming. Sandeep Bansal, M.D. will not be a member of the DSMB but may attend the meetings.

The DSMB will meet quarterly to review study data and all adverse events as described in the Registry protocol. If the DSMB identifies a safety issue, enrollment may be suspended until the issue has been satisfactorily resolved.

Privacy and Confidentiality Considerations

The REDCap data system includes password protection, dual authentication sign-on, and internal quality checks, such as automatic range checks to identify data that appear inconsistent, incomplete or inaccurate. Identifiers will be excluded in any reports that are exported from the secure data capture system. Information about study participants will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Study documents will be retained for 6 years. No records will be destroyed prior to that time.

Potential Risks and Reporting of Adverse Events Involving Risks

The primary risks are symptoms, arrhythmias, myocardial damage and data breach. All participants will undergo a device check and will be monitored during the MRI for adverse events, new or worsening symptoms. All participant data will be stored in a secure database created within REDCap, a HIPAA compliant data storage system. Any participant identifiers will be destroyed after the study is completed. Any potential breach of confidentiality would be reported to the respective

participants who were at risk, in addition to the applicable HIPAA privacy officer, the IRB and the HRPP.

Potential Benefits

The direct benefit to those participating in the study is the opportunity to receive an MRI which would otherwise not be available, and which may facilitate and guide clinical care. Indirect benefits to society may result from knowledge gained in this study.

Risk/Benefit Ratio

The potential benefits and knowledge to be gained by this study outweigh the potential risks to participants involved in this research study.

Informed Consent and HIPAA

Consent forms describing in detail the study intervention, study procedures and risks will be given to the participants and written documentation of informed consent is required prior to starting the intervention. The following consent materials will be submitted with this protocol: consent form with combined HIPAA authorization and advanced beneficiary notice.

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be IRB-approved and the participant will be asked to read and review the document. The investigator will explain the research study to the participant and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

Sponsorship

This study not funded.

Conflict of Interest

All Investigators will follow the Penn Medicine Lancaster General Health Policy on Conflicts of Interest Related to Research.

Publication Plan

After completion of the study and analysis of the data, a manuscript for publication may be written with the principal investigator as lead author. The manuscript will be targeted for publication in a clinical journal.

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