

2017

Evaluation of the Safety of MRI Scanning of Patients with MR Conditional Pacemakers

Shelly Lynn McGurk
Walden University

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Walden University

College of Health Sciences

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Shelly Lynn McGurk

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Walden University 2017

Abstract

Evaluation of the Safety of MRI Scanning of Patients with MR Conditional Pacemakers

by

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MSN, Allen College, 2011

BSN, University of Iowa, 2008

Project Submitted in Partial Fulfillment
of the Requirements for the Degree of
Doctor of Nursing Practice

Walden University

August 2017

Abstract

Magnetic resonance imaging (MRI) of patients with cardiac implantable electronic devices (CIED) has been associated with risks such as device/lead movement, device dysfunction, and lead heating. New technological advancements have made it possible for MRI to be safely performed when adhering to an evidence-based protocol; however, this practice has not yet been widely adopted. The purpose of this practice-focused question project was to examine the safety of MRI as a diagnostic modality for the aggregate population of adult patients with MR conditional pacemakers when a nurse-practitioner-led, evidence-based protocol was used. The Iowa model served as the guide for implementation of the program, and the Donabedian framework was used to evaluate the program through process, structure, and outcomes. Evidence was obtained through a documentation template that served as the procedural record in the electronic health record. Demographic information, program fidelity, and manufacturer adherence were analyzed through descriptive statistics. Clinical outcomes related to device function were measured pre- and post- MRI and analyzed with chi square and paired *t*-test inferential statistics to determine if statistically significant change occurs in the setting of MRI scanning. According to data analysis of 34 studies, there were no statistically significant changes in lead impedance, pacing thresholds, or patient reported symptoms pre- and post- MRI. The pilot program has been recommended for organizational adoption and will increase the scope of advanced practice nurses within the organization and provide the CIED aggregate population with access to an important diagnostic modality.

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Dedication

This doctoral project is dedicated to my husband and best friend, Shaun McGurk, for encouraging my endeavors, challenging me to be my best, and lifting me up when I was disheartened. All things are possible with him by my side. And our little dog too...Daphne, the original laptop.

In loving memory of Harold Wayne Stone.

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Section 1: Introduction

Introduction

Each year, more than 1 million cardiac implantable electronic devices (CIED) are prescribed throughout the world (Zikria, Machinicki, Rhim, Bhatti, & Graham, 2011). Approximately 50-75% of patients with CIED will have an indication for magnetic resonance imaging (MRI) scanning during their lifetime (Zikria et al., 2011). Historically, MRI of patients with CIED has been considered contraindicated, with multiple associated risks such as device and/or lead movement, device dysfunction resulting in changes to the program parameters and improper function, battery drain, and lead heating causing tissue damage (Beinart & Nazarian, 2012; Boilson et al., 2012). However, according to new technological advancements, recent studies, and expert opinions, MRI may be safely performed when adhering to an evidence-based protocol (Beinart & Nazarian, 2012; Boilson et al., 2012; Burke et al., 2010; Gimbel, Passman, & Kanal, 2013; Naehle et al., 2009; Shenthur et al., 2015). However, this practice has not yet been widely adopted, and the presence of a pacemaker remains a relative or absolute contraindication to MRI in many practice settings.

Physician leadership for the electrophysiology and radiology departments at a large academic medical center recommended a change in the practice paradigm of the organization and an evidence based practice protocol for MRI of MR conditional cardiac devices was written and approved for use (see Appendix A). Nurse practitioners with expertise in electrophysiology would be responsible for the implementation of this protocol using the Iowa model for evidence-based practice. The program was piloted, and

this doctoral project was designed to evaluate the pilot program to determine the safety of MRI on MR conditional cardiac devices by examining program fidelity, clinical outcomes, and patient symptoms. If the pilot of this protocol is determined to be successful, this evidence-based practice has the potential to expand the diagnostic options for the growing aggregate population of patients with CIED.

Problem Statement

MRI is a growing imaging modality and has become the standard of care for diagnosis of many conditions, such as musculoskeletal disorders, soft tissue masses, and stroke symptoms. According to Burke et al. (2010), denial of MRI scanning to patients based on the presence of CIED creates a health care disparity in which access to optimal diagnostic testing is not provided. This disparity may result in delayed or missed diagnosis, increased invasive testing, and possible harmful effects from ionizing radiation and contrast media. Hence, patients with implanted cardiac pacemakers may receive substandard care as a result of the current practice in which pacemaker patients are denied MRI as a diagnostic tool. Yamrozik et al. (2015) found that MRI performed on patients with CIED provided additional information that confirmed or changed diagnosis and/or altered medical management in 76% of neurology patients, 96% of cardiac patients, and 80% of musculoskeletal patients.

The setting for this project was a large, academic medical center that serves as the state referral center for tertiary and quaternary care. Until the implementation of the pilot program, organizational practice treated the presence of a pacemaker as an absolute contraindication to MRI scanning, and no patient with a CIED had access to the

diagnostic modality of MRI (see Appendix B). Adoption of an evidence-based protocol in which nurse practitioners with expertise in pacemaker programming manage and monitor this patient population during MRI scanning increased safe patient access to an important diagnostic modality.

The Institute of Medicine (IOM, 2010) endorsed nurses practicing to the fullest extent of their education and licensure as full members of the health care team. Expanding the role of the nurse practitioner for the application of an evidence-based protocol designed to improve safe patient access to diagnostic testing was an opportunity for nurses to make transformations in the delivery of health care. The implementation of this nurse-practitioner-led, evidence-based practice protocol required monitoring for quality and safety in alignment with the organization's strategic nursing plan that includes improvement of "patient care quality and safety through collaboration with physicians and interdisciplinary team members." The essentials of doctoral practice and competencies for acute care nurse practitioners include the integration scientific evidence to develop and evaluate new practices using a theoretical approach. Furthermore, I examined the use of technology to improve patient care in an aggregate population, safety and quality with a systems approach for leadership and management in health care systems, and a collaborative multidisciplinary teamwork (American Association of Colleges of Nursing [AACN], 2006, 2012).

Purpose

The purpose of this quality improvement project was to evaluate the safety of a nurse practitioner pilot designed to change the organizational practice paradigm to provide MRI as a diagnostic tool to patients with MRI conditional pacemakers in a consistently safe manner through the application of an established protocol for FDA approved devices.

The objectives of this quality improvement project included the following:

1. Monitoring the application of a practice guideline and the clinical indicators of device function to evaluate the consistently safe use of MRI as a diagnostic tool for patients with implanted MRI conditional pacemakers and ICDs.
2. Data collection and analysis regarding the safety and efficacy of the MRI safety protocol for a minimum of 20 patients with implanted cardiac pacemakers undergoing MRI over 6 to 12 months.
3. Presentation of the data to the electrophysiology and radiology team to determine if modifications of guidelines are needed.
4. Dissemination of results within the organization and publication of results.

These objectives served to answer the practice question: Does the implementation of a nurse-practitioner-managed, evidence-based practice protocol result in consistently safe MRI scanning of the aggregate population of patients with MR conditional cardiac devices?

Evidence used to answer the practice question was integral to determining if the change in practice paradigm should continue and increase access to a growing diagnostic modality for an increasing aggregate population. Increased access to MRI may result in more rapid and accurate diagnosis, thus reducing cost, length of stay, and potential harm from alternative diagnostic testing.

Nature of the Doctoral Project

The purpose of this doctoral project was to focus on quality improvement through the evaluation of evidence-based practice using the Iowa model for implementation. In this doctoral project, I monitored and evaluated an evidence-based practice guideline pilot in the organization and disseminated data regarding the safety and efficacy of a nurse-practitioner-administered practice guideline.

This evaluation was comprised of data collection on patients with MR conditional CIED who underwent MRI scanning. The data collected included demographic data, such as gender, age, device manufacturer, and MRI site. These data were reported using descriptive statistics. Determination if the device manufacturer check list and organizational policy was followed via a completed checklist to evaluate program fidelity; clinical indicators regarding device function were addressed through the measurement of pre and post lead impedance and threshold testing and patient report of symptoms experienced during MRI. Inferential statistics were used to examine the pre and post data for changes that determined if device function and patient symptoms remained stable. These data were collected via a standardized documentation template designed as the procedural record within the patient's electronic medical record.

Based upon data analysis that the protocol was followed, CIED function remained stable, and patients experienced minimal unpleasant symptoms. The pilot was deemed safe and appropriate for permanent practice change, thus resulting in safe access to MRI for this aggregate population.

Significance

Stakeholders associated with this quality improvement project included hospital administration, ordering providers, supervising physicians, nurse practitioners, MRI technicians, and the target population of patients with pacemakers in need of MRI diagnostic assessment. Successful and safe implementation of a pilot program led to an increase in diagnostic access within the organization, which may be generalized as a model for the organization's affiliated sites throughout the state. This also served as an opportunity for nurse practitioners in other areas to function at the upper level of their education and licensure as a member of the health care team.

The CIEDs were first used in 1958, and use has expanded to become a standard therapy for many cardiac conduction disorders (Udo et al., 2012). According to Greenspon et al. (2012), there has been an increase in the number of patients with pacemakers since 1993. As of 2009, the average age of a patient receiving a pacemaker is 75.4 years of age with some variation based on the type of device (Greenspon et al., 2012). As the age of the pacemaker patient rises, so does the number of comorbid conditions in patients. Approximately 50-75% of patients with CIED will have an indication for MRI scanning during their lifetime (Zikria et al., 2011). This represents a

significant aggregate population seeking care from multiple providers for a variety of conditions.

Lack of access to MRI may result in delay in diagnosis that can lead to advanced disease processes with detrimental effects, such as stroke and oncologic conditions. More rapid and accurate diagnosis may lead to decreased morbidity, mortality, and length of stay. There are additional costs and risks associated with use of alternative diagnostic modalities, such as those associated with ionizing radiation and contrast media; costs that may be incurred as a result of false positive or false negative results; and medico-legal ramifications for providing appropriate diagnostic testing, especially in emergency situations and for the safe performance of these exams (Lundquist et al., 2013; Santini, Giovanni, & Santini, 2013).

Medical product safety is a topic identified by Healthy People 2020 (2014) as contributing to the 10-year plan for improving the health of all people in the United States. Pharmaceuticals and medical devices are included as medical products, and this objective focuses on the appropriate use, monitoring, and manufacturing/labeling of these products as a goal to decrease adverse events and improve patient outcomes.

Summary

Although historically there have been risks such as device malfunction, lead heating/movement, and battery drain associated with MRI of patients with pacemakers, recent technological advancements, evidence from randomized controlled trials and prospective studies, and expert opinion have begun to change the practice paradigm. The presence of a pacemaker is no longer an absolute contraindication to MRI as a diagnostic

tool. The implementation of an evidence-based, nurse-practitioner-administered guideline through the science of translational research can provide the pacemaker patient population with safe access to MRI, thus improving the accuracy and timeliness of many diagnoses with decreased invasiveness and exposure to ionizing radiation and contrast media while maintaining proper device function. The Iowa model and Donabedian framework were used to apply MRI and pacemaker principles and evidence from clinical trials to the local context. Pacemaker and MRI concepts, models and theories applied to this project, and evidence found in the literature are discussed in detail in the following section.

Section 2: Background and Context

Introduction

There is an increasing cohort of individuals with CIED who are denied access to the diagnostic modality of MRI. This quality improvement project was designed to evaluate an evidence-based pilot program for MRI of MR conditional CIED and answer the following question: Does the implementation of a nurse-practitioner managed practice protocol result in consistently safe access to MRI as a diagnostic tool for patients with MR conditional pacemakers? In this section, I review the current literature, protocols, and the theoretical model used for the evaluation of the pilot program.

Concepts, Models, and Theories

The technical concepts of MRI and pacemakers were integral to the formation of the protocol used in this project. The Iowa model and Donabedian framework served as the guides for implementation and evaluation of the protocol.

MRI Concepts

Van der Graaf, Bhagirath, and Gotte (2014) described the function of the MRI as follows: The MRI consists of a magnetic, gradient, and radiofrequency transmitter coils (Van der Graaf et al., 2014). The magnetic coil generates a strong and constant magnetic field. The strength of this magnetic field is described in units called Tesla (Van der Graaf et al., 2014). Gradient coils are also present inside the main magnet that are switched on and off. The radiofrequency coil produces a magnetic field that delivers energy to hydrogen protons. The static and radiofrequency fields create resonance signals that are captured by receiving coils and provide detailed image reconstruction of tissue

characteristics (Van der Graaf et al., 2014). The amount of energy the individual receives is described as specific absorption rate (SAR; Van der Graaf et al., 2014)). The SAR is proportional to the static magnetic field strength; hence, a relationship between magnetic field strength and scan time determine the amount of energy a patient absorbs.

MRI and Pacemaker Risks

There have been 17 MRI-associated deaths in patients since 2007 (Zikria et al., 2011). Gimbel et al. (2013) reported that due to potential legal action, MRI-associated deaths and complications are likely not sufficiently documented. Magnetic resonance uses static magnetic, gradient magnetic, and radiofrequency fields in order to generate images. All of these fields have the potential to interfere with the function of the pacemaker and/or cause tissue damage (Cronin, Mahon, & Wilkhoff, 2012). In vitro, MRI examination affects pacemaker function, electrocardiography (EKG) readings, and battery life (Zikria et al., 2011).

Reed switch malfunction. Many CIED have a magnetic reed switch that consists of metal strips encapsulated in glass. These magnetic strips switch on or off when exposed to a magnetic force (Jacob et al., 2011). Closing of the switch triggers the pacemaker to respond by performing programmed functions, such as asynchronous pacing or suspending tachycardia therapies, and can also result in battery depletion (Jacob et al., 2011). In a systematic review of pacemaker complications associated with MRI, Zikria et al. (2011) reported two in vitro and four in vivo studies demonstrating reed switch activation when exposed to the static magnetic field of an MRI scanner. Some scholars found variation in activation based on positioning within the magnetic

field. Vahlhaus et al. (2001) found that all pacemaker patients undergoing MRI had reed switch activation with 37.5% having deactivation when positioned in the center of the scanner. The reed switch is affected by position to the magnet. Closure of the reed switch may lead to asynchronous pacing at a default rate which, originally designed as a safety feature, can be harmful if continued for a prolonged period of time (Cronin & Wilkhoff, 2012).

Many newer pacemaker models, often referred to as modern pacemakers, have alternative technology to replace the reed switch such as giant magnetosensitive resistors (GMR), telemetry coils, or Hall-effect sensors (Jacob, 2011). This is one feature change found in the design of MR conditional pacemakers.

Lead heating. The radiofrequency field of the MRI can cause lead tip heating resulting in myocardial edema or scarring. This damage can result in loss of pacing capture in the cardiac tissue or potential arrhythmias (Beinart & Nazarian, 2012; Boilson et al., 2012). Langman, Goldberg, Finn, and Ennis (2011) conducted an in-vitro study to determine factors contributing to lead heating and found that lead termination and length had the most impact on temperature change. Thus, MRI should not be performed on patients with abandoned leads.

Device dysfunction. Electrical current induction and electromagnetic interference have been demonstrated in multiple in vitro and animal studies. Both phenomena occur in the MR environment as a result of radiofrequency fields and pulsed gradients (Cronin & Wilkhoff, 2012). These electrical disturbances may result in incorrect pacemaker diagnostics or rapid capture of myocardium which, in turn, result in pacing inhibition;

rapid ventricular pacing; or power-on resets that have the potential to cause tachy-arrhythmias, hemodynamic compromise, inappropriate therapies, and battery drain.

Iowa Model

The evidence-based practice model used to integrate the practice change of performing MRI scans on CIED patients with a safety protocol was the Iowa model. The model served as a framework for applying evidence to practice with a systematic, iterative approach. The steps of the Iowa model include triggers to identify a clinical problem; determination of organizational priority; team formation; critique and synthesis of literature; piloting change; adopting practice; and ongoing analysis and evaluation of structure, process, and outcomes (Titler et al., 2001).

Applying the current evidence based practice (EBP) project of a MRI safety protocol for scanning patients with CIED was as follows. The trigger was the identified need in which providers were unable to obtain the diagnostic information needed via MRI due to absolute contraindication based on CIED and the recent FDA approval of MR conditional devices. The need for safe MRI of CIED was identified by both the cardiology and radiology departments as an organizational priority. An appropriate team for the MRI protocol was comprised of a representative from electrophysiology, radiology, MRI technicians, advanced practice provider responsible for monitoring the test, scheduling, billing, and informatics specialists. Once the protocol was established, a piloting program with iterative feedback was initiated and monitored. Figure 1 depicts the program development used for MRI of pacemaker patients using the Iowa model.

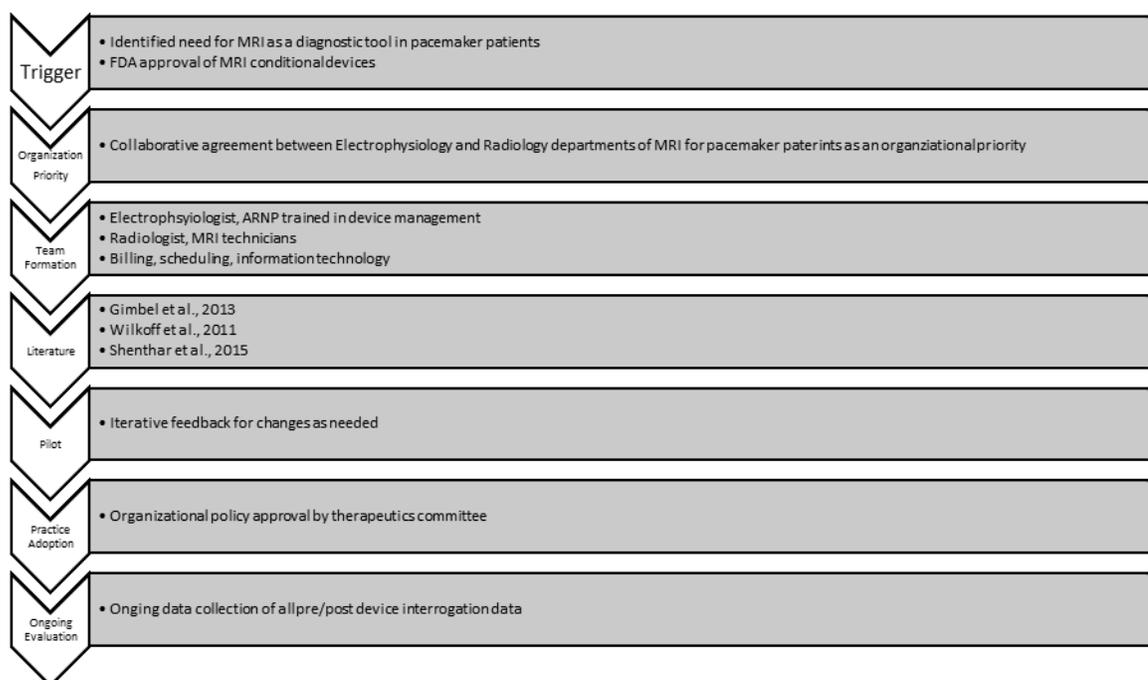


Figure 1. MRI for pacemaker patients using the Iowa model.

Adapted from “The Iowa Model of Evidence-Based Practice to Promote Quality Care,” by M. Titler, C. Kleiber, V. Steelman, B. Rakel, G. Budreau, and L. Everett, 2001, *Critical Care Nursing Clinics of North America*, 13(4), p. 500.

Donabedian Framework

The evaluation and analysis process of the Iowa model is supported by the Donabedian framework for quality, which examines structure, process, and outcomes (Donabedian, 1978). Interactions among providers and patients make up process. Structure refers to the environment, equipment, and resources with which the providers work. The actual change in the current and future health for a patient/population based on process and structure is the outcome (Donabedian, 1978).

When the Donabedian framework was applied to the project, structure was comprised of the trained personnel performing and monitoring the test, appropriate MRI equipment, device interrogation equipment, and emergency equipment. The consistent application of the protocol, scheduling, prescreening, documentation, and billing comprised the process. Evidence that demonstrated safe and acceptable pre and post scan device settings and function and presence or absence of adverse patient outcomes were data supporting safe outcomes and an increase in overall number of MRI scans demonstrated increased access. Figure 2 depicts the Donabedian framework applied to the program for MRI of pacemaker patients.

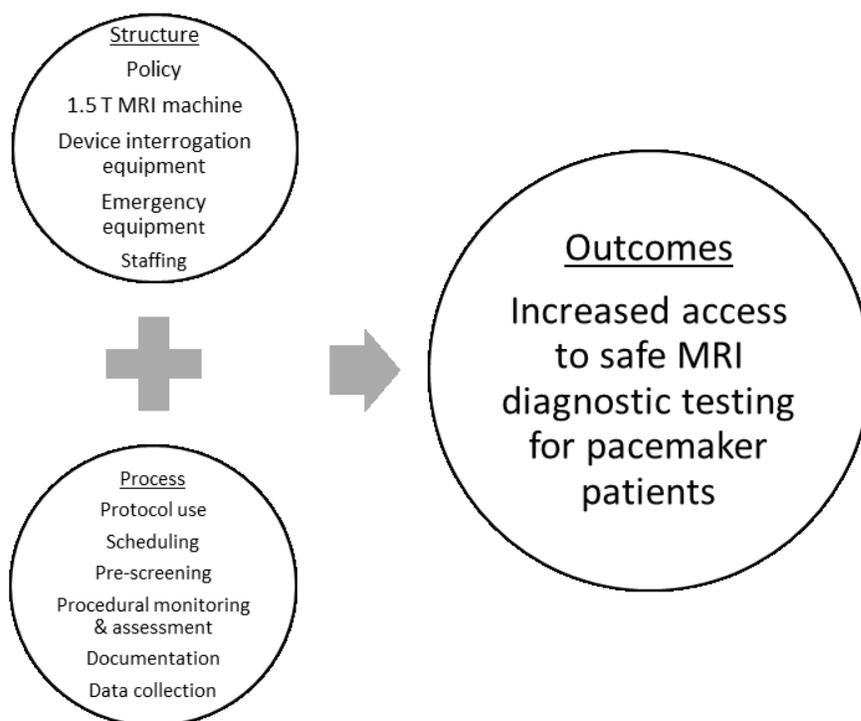


Figure 2. Theory application Donabedian framework.

Adapted from “The Quality of Medical Care,” A. Donabedian, 1978, *American Association for the Advancement of Science*, 200(4344), 856-864.

Relevance to Nursing Practice

The implication for advanced nursing practice was the advancement of the scope of practice for nurse practitioners at the organization and evaluated the safety and efficacy of the program in providing the CIED aggregate population with access to MRI as a diagnostic modality. Allowing advanced practice nurses to expand their practice to encompass new programs provides the opportunity to practice to the fullest extent of education and licensure and contribute as full members of the health care team as recommended by the IOM (2010). Expanding the role of the nurse practitioner for the application of an evidence-based protocol designed to improve safe patient access to diagnostic testing provided an opportunity for nurse practitioners to transform an area of health care delivery by decreasing a disparity in access and increasing medical product safety through appropriate monitoring. The essentials of doctoral practice and competencies for acute care nurse practitioners include the integration scientific evidence to develop and evaluate new practices using a theoretical approach. Furthermore, I examined the use of technology to improve patient care in an aggregate population, safety and quality with a systems approach for leadership and management in health care systems, and collaborative multidisciplinary teamwork (AACN, 2006, 2012).

The translation and integration of evidence into clinical practice was integral to improving access to a diagnostic technology, MRI, for a growing aggregate population of aging patients with implanted CIED. As this aggregate population continues to expand with increasing comorbid conditions, the need for MRI as a diagnostic modality will become more prevalent. Denial of access to MRI may result in delayed or missed

diagnosis, which may have a myriad of implications for outcomes. This social change will serve as a bridge to the health care access disparity that exists for patients with implanted devices that are currently denied access to MRI diagnostic modalities.

Professional organizations and clinical trials support the decision of the organizational leadership to change the practice paradigm. Ongoing evaluation was needed to demonstrate safe implementation of the new practice.

Guidelines and Protocols

The American Heart Association (AHA) published guidelines for MRI safety in CIED in 2007 (Levine et al., 2007). The AHA indicated that the presence of a pacemaker is a strong relative contraindication for MRI scanning and recommended doing so only if there is a significant clinical indication with additional cautionary statements for pacemaker dependent patients and those with internal cardiac defibrillators (ICD; as cited in Levine et al., 2007). The recommendations include informed consent, presence of an advanced cardiac life support (ACLS) and pacemaker experienced physician, consultation with radiology for lowest possible magnetic gradient, pre and post MRI device interrogations, continuous patient monitoring throughout the exam, and emergency equipment availability throughout the exam. Most of the study protocols found in clinical trials have been developed around the AHA recommendations with some variations in the monitoring staff and device interrogation techniques. Researchers have determined the effect of MRI on CIED and a safe method for proceeding with MRI scanning in those with CIED. The AHA has not yet updated guidelines for MRI of

pacemakers since the U.S. Food and Drug Administration (FDA) approval of MR conditional devices in 2011.

On February 8, 2011, the FDA (2011) conditionally approved the first pacemaker that was considered safe under specific conditions. The FDA also required a post market study in which chronic lead performance and device function are followed for a minimum of 5 years (Mitka, 2011).

The American College of Radiology (ACR, 2013) recommended following the manufacturer's guidelines for the MR conditional device in place as there are differences in the device programming based on brand. The ACR recommended that all implanted hardware be verified through prescreening verification with the manufacturer of the device. Additional guideline recommendations that are applied to both MR conditional and non-MR conditional devices included signed informed consent, prescreening for device and leads including abandoned leads, consultation with cardiology, pre and post device interrogation, availability of emergency equipment, and 1-3 month follow up.

Clinical Trials

Prospective observational clinical trials have supported safe MRI of patients with CIED when selected and monitored with a safety protocol. Beinart and Nazarian (2012) conducted a large ($n= 438$) prospective study in which they developed a protocol for selection process and pacemaker testing with reprogramming pre and post MRI and continuous monitoring throughout the scan. There were statistically significant but clinically minor changes in devices. There were no long-term affects to the pacemaker function. Beinart and Nazarian concluded that protocol-based MRI in patients with

pacemakers was safe under conditions. Similarly, Boilson et al. (2012), in a smaller prospective study ($n=32$), identified “power-on” resetting of pacemaker devices in five patients with no adverse events noted. Hence, Boilson et al. endorsed the need for close patient monitoring and device assessment with scanning to maintain safety. Naehle et al. (2011) conducted a prospective trial ($n=32$) of patients with pacemakers undergoing cardiac MRI and found the risk/benefit ratio acceptable on those with right-sided devices but unfavorable on left-sided devices due to the artifact generated limited diagnostic imaging quality.

The largest ongoing clinical trial examining MRI and pacemaker safety is the Magna Safe Registry. This is a prospective multicenter study in which patients with pacemakers or ICDs implanted after 2001 undergo nonthoracic MRI exam as clinically warranted using a protocol (Russo, 2013). Preliminary study results were presented at the American College of Cardiology (ACC, 2014) and revealed that of the 1,500 cases enrolled, only one ICD patient experienced device failure requiring urgent replacement, and this was found to be due to inappropriate programming of the device prior to exam. There were six incidences of atrial fibrillation/flutter and no ventricular arrhythmias documented. The findings of this study will change practice guidelines and reimbursement practices from the Centers for Medicare and Medicaid Services (CMS).

Advances in technology have resulted in FDA approval of MRI conditional CIED. In 2011, the FDA approved the first MRI conditional device for use (U.S. Food and Drug Administration, 2011). The term MRI conditional is defined as “devices deemed safe under pre-specified MRI conditions” (Kodali, Baher, & Shah, 2013, p. 137).

These devices include features such as reduced ferromagnetic content, replacement of reed switch technology, modification of lead tips to reduce heating, shielding of circuitry to prevent electrical interference, and MRI programming modes (Cronin & Wilkhoff, 2012). Random controlled trials have been conducted to assess the safety of MRI conditional devices.

Gimbel et al. (2013) conducted a randomized controlled trial in which 236 patients were randomized in a 2:1 ratio for MRI scanning after placement of an MRI conditional pacemaker system and found no MRI related complications and no significant differences in pacemaker capture thresholds between groups. Wilkhoff et al. (2011) also found in a randomized controlled trial ($n=464$) no MRI related complications during or after MRI scans in patients with MRI conditional devices and concluded that the specialty dual chamber pacemaker could be exposed to MRI at 1.5T without adverse patient outcomes or pacemaker system function. Shenthur et al. (2015) conducted a randomized control trial in which 266 patients were randomized at a 2:1 ratio for MRI scanning 9-12 weeks after implantation of the MRI conditional Medtronic Novus 5076 lead. Shenthur et al. concluded that MRI can be safely performed without restriction to position when these pacemaker leads were connected to an MRI conditional device. In a study examining the effect of MRI on MRI conditional ICDs, Gold et al. (2015) found no MRI complications, no differences in pacing and sensing amplitudes, and no impact on detections and therapy delivery between groups.

Local Background and Context

In 2011, the FDA approved the first pacemaker that is conditionally MR safe under specific conditions (FDA, 2011). However, few organizations offer MRI of pacemaker patients despite the new technology. The project site maintained the policy that the presence of a pacemaker was an absolute contraindication to MRI. This policy included a hard stop in the electronic medical record for ordering the exam if a pacemaker was present (See Appendix B). There was an increase in electrophysiology consults requesting assistance with diagnostic imaging recommendations for patients with CIED; and therefore, a multidisciplinary team was formulated to develop a policy to address the issue.

The project site was a 732-bed level 1 trauma medical center that serves as the state's referral resource for advanced tertiary and quaternary care. Therefore, it was necessary to provide current diagnostic options in order to provide the best possible quality care to patients. This change in the practice paradigm had the potential to impact an aggregate population of residents throughout the entire state.

Definition of Terms

The following are operational definitions used for this project:

1. Abandoned leads. Pacemaker leads that were retained in the body but no longer attached to a generator.
2. Device function. Lead impedance and pacing thresholds were used to define device function. Appropriate device function was determined by lead

impedance between 200-1500 ohms (Ω) and a pacing threshold of <2.0 V at 0.4 ms with < 0.5 V change upon repeat testing.

3. MR conditional. Items were considered safe in the MRI environment when specific conditions of use were met (ACR, 2013). For the purpose of this project a MR conditional pacemaker was an entire system that included generator, leads, and all connecting devices that met the MR conditional requirements. The presence of any leads, extenders, or connectors that were not MR conditional rendered the entire system not MR conditional.
4. Pacemaker. The term pacemaker encompassed the implanted generator and lead system which produces low voltage electrical impulses to manage cardiac conduction disorders. This included devices with or without defibrillator capabilities (Kenny, 2008).

Role of the DNP Student

As an acute care nurse practitioner in the adult cardiovascular internal medicine hospitalist program, I have encountered patients with CIED and co-morbid conditions requiring MRI as a diagnostic modality which increased the complexity of management. These cases prompted a review of the literature regarding MRI in pacemaker patients, and consultation with the Electrophysiology (EP) service. The EP service nurse practitioner revealed that, based on the recommendations of the electrophysiology and radiology physicians, there were plans to develop an organizational policy for this aggregate population. The EP nurse practitioner agreed to serve as my preceptor for doctor of nursing practice (DNP) studies. Practicum experiences included learning

pacemaker technology/function, participating in the development of a policy/workflow for MRI of pacemaker patients, and educating ordering providers. This project was approved by the healthcare organization for piloting. For my capstone project, I collected data from the records of the patients undergoing MRI of MR conditional devices, and evaluated the data for consistent application of the protocol, device function outcomes, and patient-reported symptoms.

Summary

The FDA approved MR conditional pacemaker technology in 2011 (FDA, 2011). This advance in technology has been supported with clinical trials and professional organization guidelines. Until recently, the organizational site continued to deny pacemaker patients access to MRI based on a policy in which the presence of a pacemaker was an absolute contraindication to MRI. However, a change in practice was initiated and the policy was changed to include MRI scanning of MR conditional cardiac devices with the use of an evidence-based practice protocol. This protocol was piloted and evaluated to ensure consistent and safe implementation through the collection of evidence regarding program fidelity and CIED function. A documentation template was developed in order to collect data which were analyzed using both descriptive and inferential statistics. Next, the data collection and analysis plan will be discussed in detail.

Section 3: Collection and Analysis of Evidence

Introduction

There is an increasing cohort of individuals with CIEDs who are denied access to the diagnostic modality of MRI. New technology, supported with evidence from clinical trials and professional organization guidelines, has led to a change in the practice paradigm resulting in the implementation of an evidence-based practice protocol pilot for MRI of MR conditional devices. This quality improvement project was designed to evaluate the pilot and answer the following question: Does the implementation of a nurse practitioner managed practice protocol result in consistently safe access to MRI as a diagnostic tool for patients with MR conditional pacemakers? In this section, I review the methods, data collection, and evaluation intended to provide evidence regarding the safety of the newly implemented protocol.

Practice Focused Question

Until the implementation of the pilot program, organizational practice treated the presence of a pacemaker as an absolute contraindication to MRI scanning, and no patient with a CIED had access to the diagnostic modality of MRI (see Appendix B). Adoption of an evidence-based protocol in which nurse practitioners with expertise in pacemaker programming managed monitors this patient population during MRI scanning has the potential to increase safe patient access to a diagnostic modality. The purpose of this project was to evaluate a pilot protocol to determine patient demographics, program fidelity, and appropriate device function.

Sources of Evidence

The health facility adopted a new clinical practice to allow adult patients with an MR conditional pacemaker, a clinical indication, and a provider order for MRI to be allowed access to an MRI. Prior to MRI, the patients were screened by the nurse practitioner for inclusion/exclusion criteria for MRI scanning based on the evidence-based established criteria and the manufacturer recommendations for the device implanted in the patient. Inclusion criteria included patients over the age of 18 with permanent MR conditional pacemaker device and lead systems implanted for greater than 6 weeks with a clinical indication for MRI diagnostic evaluation and no additional contraindication to MRI scanning or the presence of exclusion criteria. Exclusion criteria included those less than 18 years of age, less than 6 weeks since CIED implantation, all components of the pacemaker system were not FDA approved as MR conditional, fever, or the presence of additional contraindications to MRI. Those with abandoned leads were also excluded regardless of MR conditional status. Additional contraindications were based on the manufacturer recommendations for the implanted device

Data were obtained via the medical records of these MRI patients. A record of the procedure was included in the electronic medical record using a template. These data were evaluated for adherence to protocol and pre and post device function. The cumulative clinical indicator data were used in a summative manner to evaluate overall safety and efficacy of the protocol. Data collected included gender, age, device manufacturer, MRI body site, pre and post MRI device thresholds, pre and post MRI lead impedance, and patient reported device-associated symptoms during the MRI.

A template was created to document within the patient record appropriate screening, device function, monitoring, and scanning. The use of documentation templates captured the necessary data elements (see Appendix C). This standardized documentation was completed by the provider responsible for device programming and patient monitoring during the MRI scan. This served as the procedural note in the patient record and supported billing to ensure that the organization could optimize reimbursement for the care delivered. Use of one documentation template to serve multiple purposes decreased the likelihood of missing elements.

Protection of Human Subjects

In 2003, the Hastings Center convened experts to address ethical issues associated with quality improvement (QI) methods in the United States. The group defined QI and the ethical requirements for QI activities. QI was defined as “systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings” (Lynn et al., 2007, p. 667). QI is focused on actions designed to improve care supported by data as a reflection of effect and is considered both necessary and normal for health care operations. Improving quality of care is considered an ethical responsibility of health care providers. As such, consent to receive care often implies participation in QI unless such participation would subject the individual to additional surveys and/or medical procedures. Lynn et al. (2007) provided the examples of introduction of procedures to reduce medical errors or adoption of new guidelines as QI activities. The program for MRI of pacemakers fell into this category as the procedure is not experimental, was approved by the FDA in 2011, and was recognized by CMS as a

reimbursable procedure. The design of this program was to ensure that recommended guidelines were followed in a consistent manner for quality and safety.

The organizational internal review board granted a waiver stating that this project does not meet the regulatory definition of human subject research as it is a QI project involving the evaluation of expanded practice guidelines approved by the medical practice committee.

Analysis and Synthesis

Evaluation is an ongoing process designed to provide information regarding program implementation; effectiveness; efficiency; cost effectiveness; and attribution for the purpose of description, improvement, adaptation, and decision making. A formative evaluation was performed to determine if the program goals were attained (Hodges & Videto, 2011). A formative evaluation involves using data to develop or improve a program (Hodges & Videto, 2011). The data in a formative evaluation are used to test “plans, messages, materials, procedures, and modifications to existing programs” (Hodges & Videto, 2011, p. 207). This evaluation is used to examine pilot testing for unexpected problems or outcomes. The evaluation was comprised of indicators of adherence to manufacturer recommendations, stable device function, and patient-reported symptoms. If the evaluation demonstrated that these indicators support the safety and efficacy of MRI scanning for this aggregate population, then the nurse-practitioner-led program will be formally adopted as a practice change as outlined in the Iowa model for the adoption of evidence-based practice.

Demographic Data

A summary of the sample for this project was provided through descriptive statistics (Terry, 2015). A distribution of the age, gender, device manufacturer, and body area scanned were used to describe the sample population undergoing MRI. This descriptive data provided a demographic illustration of the patients in this program. The demographic data were analyzed and reported using descriptive statistics and reported means and frequency distribution.

Program Fidelity

The guidelines for MRI of MR conditional devices recommend adherence to manufacturer specifications for scanning. The device specifications, while often similar, do have variation. Therefore, assessment of the screening criteria allowing evaluation of use of appropriate prescreening criteria is an outcome to demonstrate appropriate application of the program by the nurse practitioner. The criteria for each device manufacturer were embedded in the documentation template, and the provider selected the criteria based on the device. All criteria had to be met in order to be considered appropriately screened. The screening criteria were collected as nominal data with a yes/no response. Frequency distribution demonstrated how often the screening criteria were completely met.

Clinical Indicators

Planas (2008) reported that clinical indicators are considered the main source for measuring effectiveness. Clinical indicators to assess the successful implementation of a protocol for MRI on MR conditional pacemaker patients included device function

pre/post MRI scan and patient reported symptoms during MRI scan. This clinical indicator measurement was achieved through device interrogation completed by a nurse practitioner with measurement of thresholds and lead impedance for each implanted lead before and after MRI scanning. The clinical indicators of device function were collected and evaluated in an ongoing manner with data for each patient collected and analyzed. This information was located within the body of the documentation template.

Lead impedance is the amount of resistance to the flow of electrical current from the cardiac-implanted electrical device through the lead, and it is a predictor for device longevity and function (Kenny, 2008) Acceptable impedance range is 200-1500 ohms (Ω). Low lead impedance could indicate a defect in the insulation of the lead while high lead impedance is often associated with lead damage, lead fracture, or loose setscrew (Hayes, Asirvatham, & Friedman, 2013). Due to the range for lead impedance for acceptable device function, these data were collected as nominal data in which yes indicates lead impedance within acceptable range and no indicates lead impedance outside of the acceptable range. Further assessment was performed by using a paired *t*-test to determine if there was a statistically significant change in means between pre and post MRI exposure. These data were measured in ohms.

Kenny (2008) defined pacing thresholds as “the minimum amount of energy required to reliably capture (cause depolarization of) the heart” (p. 161). Determining the pacing threshold allows for programming with a safety margin to ensure capture and appropriate pacing. Increased thresholds will decrease the longevity of the device through battery depletion as a result of increased electrical output. Pacing thresholds are not

static, and there will be ongoing variability; hence, an increase of greater than 0.5 V @ 0.4 ms is the established parameter of a threshold change requiring further evaluation. Medication, electrolyte imbalance, new myocardial infarction/tissue damage, and lead dislodgement are the most likely causes of variation in pacing thresholds (Hayes et al., 2013). A paired *t*-test was used to make inferences regarding pre and post threshold measurements.

Professional guidelines and manufacturer recommendations for MRI and MR conditional devices include ongoing verbal communication with the patient to assess for any symptoms experienced during the MRI scan. These data were collected in the format of yes/no answer for patient reported symptoms. The documentation template included free text for a description of symptoms in the event that these data would require further analysis. These data were collected as nominal data and reported with a frequency count. A McNemar chi square test was performed to compare the presence of symptoms pre and post MRI.

Summary

This new nurse practitioner, evidence-based protocol was applied to patients with MR conditional pacemakers. As a QI project based on an existing protocol, this project was exempt as human subjects research.

Descriptive statistics, program fidelity, and clinical indicators were examined as part of a formative evaluation. Data collected included device type, MRI site, adherence to manufacturer recommendations, pre/post device interrogation parameters, and patient-reported symptoms. The documentation template for MRI of pacemaker patients

contained the descriptive data, documentation of adherence to manufacturer guidelines, pre/post device interrogation findings, and any symptoms reported by the patient. The collected data were analyzed with descriptive and inferential statistics in order to make a determination regarding the safety of the pilot protocol.

The following is a discussion of the findings and implications based on the data analysis, recommendations, and areas identified for future study.

Section 4: Findings and Recommendations

Introduction

There is an increasing cohort of individuals with CIEDs who are currently denied access to the diagnostic modality of MRI. New technology, supported with evidence from clinical trials and professional organization guidelines, has led to a change in the practice paradigm resulting in the implementation of an evidence-based practice protocol pilot for MRI of MR conditional devices. This QI project was designed to evaluate the pilot and answer the following question: Does the implementation of a nurse practitioner managed practice protocol result in consistently safe access to MRI as a diagnostic tool for patients with MR conditional pacemakers? This section provides a discussion of the data analysis findings and implications, recommendations, and strengths and limitations. Data collection included age, gender, device manufacturer, MRI site, use of manufacturer checklist, pre and post MRI lead impedance and pacing thresholds, and patient-reported symptoms. The data were collected via chart review and analyzed using SPSS software.

Findings and Implications

Data were collected for MRI performed on MR conditional CIED via the electronic medical record. The data were de-identified and compiled in an Excel spreadsheet and analyzed using SPSS software. An analysis of the data included descriptive data regarding age, gender, device manufacturer, MRI site, and use of manufacturer checklist. Categorical data were reported in frequencies and percentages, and continuous data were reported in means. Inferential statistical analysis including paired *t*-tests, and McNemar chi square was used to analyze the clinical outcome data

including pre and post MRI lead impedance, pacing thresholds, and patient-reported symptoms.

Descriptive Data

A total of 34 MRI scans were performed on 29 patients with MR conditional pacemakers between June 2016 and April 2017. Five of the MRI scans performed were repeat scans on patients requiring MRI surveillance of a condition or MRI for another indication. Repeat MRI scans were not addressed in the original policy, and there was concern that repeated exposure to radiofrequency fields could have a cumulative effect on device function. Russo et al. (2012) used Magna Safe Registry data in which 12% ($n=43$) of the patients had undergone more than one MRI and up to as many as seven and determined that there was no association between the number of MRI scans and adverse effects to the patient or device. Later analysis of the same registry was published with report of as many as 11 MRI scans in one patient (Russo et al., 2017). The median interval between repeated scans was 153 days (Russo et al., 2017). There were no clinically significant differences in patients who underwent repeated scanning versus those who had a single MRI scan; however, there were changes to the shock lead impedances in patients with ICDs (Russo et al., 2017). These changes required no intervention (Russo et al., 2017). The devices in the Magna Safe study were not MR conditional, whereas those in the pilot program were all labeled MR conditional.

There were 20 (59%) male and 14 (41%) female patients with a mean age of 65.7 years and a median age of 66 years. This age was younger than the average age 75.4 years at which pacemakers are implanted (Greenspon et al., 2012).

The group was comprised of patients with three MR conditional device manufacturers: Medtronic (47%), Biotronik (41%), and Boston Scientific (12%). The variation in the representation of manufacturers was likely due to the amount of time each brand has been available on the market leading to more devices implanted. This variation was likely due to the dates in which FDA approval was granted for the technology with Medtronic receiving initial approval in 2011, Biotronik in 2014, and Boston Scientific in 2016 (Biotronik, 2014; Boston Scientific, 2016; FDA, 2011). This variation may also be a result of regional implanting provider preferences and purchasing contracts. Figure 3 illustrates the device manufacturers represented in the program pilot.

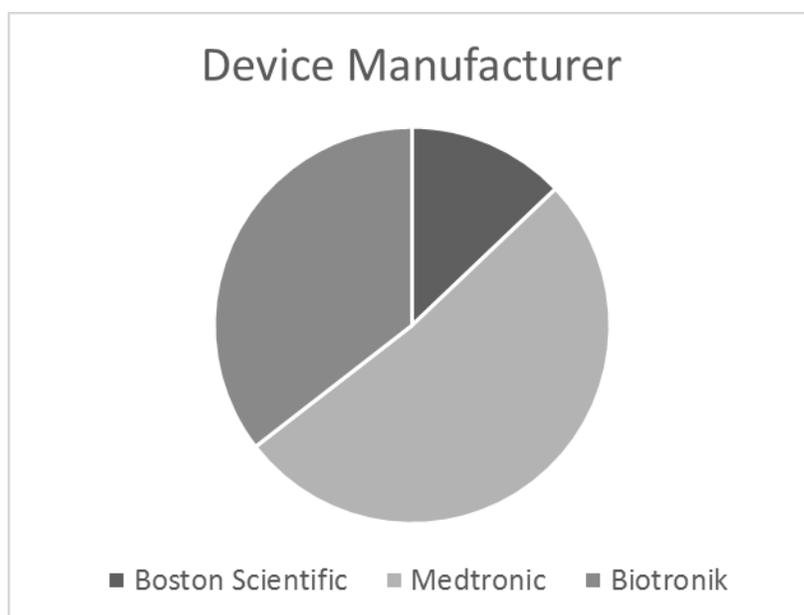


Figure 3. Device manufacturer.

In some cases, more than one body area was scanned per patient for a total of 38 anatomical sites. The anatomical areas scanned included 52.6% brain, 28.9% spine, 7.9% abdomen/pelvis, 7.9% lower extremity, and 2.6% other. Brain and spine imaging comprised 81% of the sample. This was consistent with findings in studies of MRI and pacemakers with 75% of MRI scans in the Magna Safe registry and 89% in a single center trial targeting brain and spine as the anatomical site scanned (Russo et al., 2017; Strom et al., 2017).

There were no MRI scans involving thoracic sites during the pilot program. Scholars have demonstrated that full body scanning is safe for appropriate pacemaker function (Gimbel et al., 2013; Naehle et al., 2011). However, Naehle et al. (2011) reported that image quality and diagnostic value may be decreased as a result of the ferromagnetic material interference in the views needed for cardiac MR and other structures in the thoracic region. Thoracic imaging was excluded from the Magna Safe Registry study (Russo et al., 2017). Horwood et al. (2017) conducted a study using CIED and MRI conditions that have been excluded in previously published studies and found that of 94 patients who underwent cardiac MRI, four of those studies were considered nondiagnostic due to extensive artifact related to device proximity.

The largest number of MRI referrals were generated for neurological symptoms leading to MRI of the brain and/or spine. However, increased education and awareness regarding the pilot program may lead to an increase in referrals from other services for varying symptoms and conditions. Figure 4 depicts the MRI scan sites in the pilot.

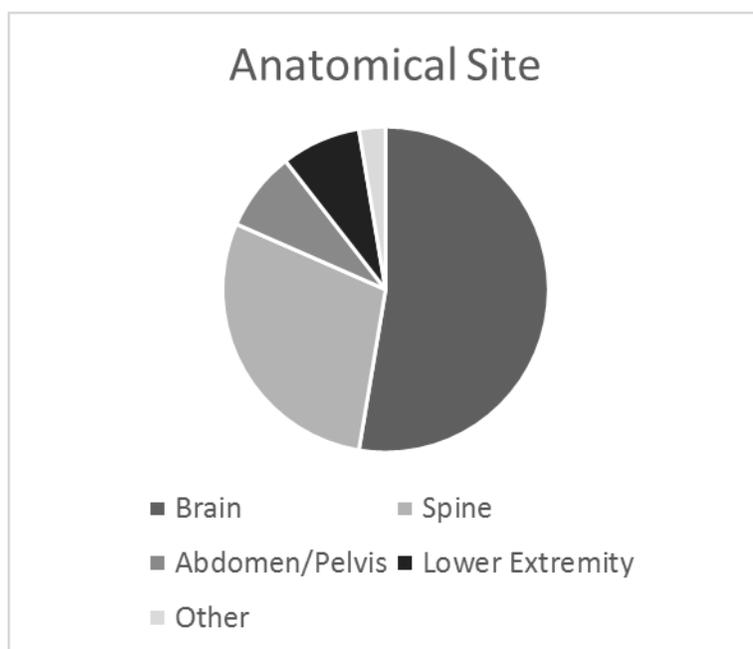


Figure 4. Anatomical site.

Program Fidelity

Program fidelity was evaluated by determining if manufacturer specifications were met during the prescreening evaluation of the patient. In 94% of all cases, the manufacturer recommendations were met. In the two cases that did not meet prescreening requirements, the ventricular lead threshold exceeded 2.0 V @ 0.4 ms. Each of these cases were reviewed by the electrophysiology team, and it was determined that the pacemaker settings did not require the lead in question in order to function properly and the patient was not pacemaker dependent. There was no change in device lead function post scan.

Clinical Indicators

Clinical indicators for this project were measures of CIED function based on measurement of pacemaker lead impedance and lead thresholds obtained through device

interrogation for each implanted lead before and after MRI scanning. Langman, Goldberg, Finn, and Ennis (2011) reported that lead tip heating due to radiofrequency fields generated by MRI is dependent on lead length and termination condition (i.e., attached or unattached). Therefore, changes in lead impedance and pacing thresholds pre and post MRI were examined separately for atrial and ventricular leads as ventricular leads are longer than atrial leads. Additionally, not all pacemaker systems are comprised of an atrial lead.

Lead impedance. Lead impedance is not static, and there will be ongoing variability; hence, there are established acceptable parameters for evaluation. Recommended lead impedance range is 200-1500 ohms (Ω) (Hayes et al., 2013). An increase of 50 Ω should generate further investigation of device function (Russo et al., 2017). During the pilot, no lead impedance measurements pre or post MRI scan were outside of the acceptable range.

The change in lead impedance was further examined with a paired *t*-test. This parametric test is designed to examine the difference in two paired means at two different times such as pre and post MRI (Polit, 2010). As shown in Table 1, the *t*-test revealed that the pre MRI atrial lead impedance mean ($M= 524.8$) was not significantly different post MRI ($M = 516$), $t(22) = 1.09$, $p = 0.29$. The *t*-test revealed that the pre MRI ventricular lead impedance mean ($M= 556.2$) was not significantly different from post MRI ($M = 573.8$), $t(26) = -1.39$, $p = 0.17$.

Table 1

Paired t-test Results for Lead Impedance

	Pre MRI Mean (<i>SD</i>)	Post MRI Mean (<i>SD</i>)	<i>t</i>	<i>df</i>	<i>p</i>
Atrial Impedance	524.8 (116,3)	516.0 (100)	1.09	22	0.29
Ventricular Impedance	556.2 (122.6)	573.8 (101.7)	- 1.39	26	0.17

Pacing thresholds. Pacing thresholds are not static, and there will be ongoing variability in measurement (Hayes et al., 2013). The acceptable change in pacing threshold for each lead is 0.5 V @ 0.4 ms. In the pilot program, there were no changes outside of the acceptable recommendation for pacing thresholds.

The change in pacing thresholds were further examined with a paired *t*-test. This parametric test is designed to examine the difference in two paired means at two different times such as pre and post MRI (Polit, 2010). As shown in Table 2, the *t*-test revealed that the pre MRI atrial lead pacing threshold mean ($M = 0.8$) was not significantly different post MRI ($M = 0.78$), $t(22) = 0.64$, $p = 0.52$. The *t*-test revealed that the pre MRI ventricular lead pacing threshold mean ($M = 0.94$) was not significantly different from post MRI ($M = 0.87$), $t(27) = 1.66$, $p = 0.11$.

Table 2

Paired t-test Results for Pacing Thresholds

	Pre MRI Mean (<i>SD</i>)	Post MRI Mean (<i>SD</i>)	<i>t</i>	<i>df</i>	<i>p</i>
Atrial Threshold	0.8 (0.28)	0.78 (0.23)	0.64	22	0.53
Ventricular Threshold	0.94 (0.42)	0.86 (0.33)	1.66	27	0.11

Therefore, the null hypothesis was confirmed that there was no significant change in MR conditional pacemaker function based on the clinical indicators of lead impedance and pacing thresholds associated with MRI exposure.

Patient-Reported Symptoms

The occurrence of pacemaker-associated symptoms, such as dizziness, presyncope, palpitations, or warmth/vibration at the pacemaker site were documented within the patient record, and during data collection, they were recorded as symptomatic or asymptomatic. One patient was experiencing intermittent symptoms related to pacemaker settings upon arrival for MRI, and two patients reported symptoms during the MRI. A McNemar chi square was performed to assess the pre and post MRI incidence of patient-reported, pacemaker-associated symptoms, and there was no statistically significant difference in the presence of symptoms pre and post MRI, $p = 1.00$. This result should be interpreted conservatively as the recommended minimum frequency of cases in all crosstabulation cells is 5, and this condition was not met (Polit, 2010). Therefore, the

null hypothesis that patients will have no increased pacemaker associated symptoms with MRI exposure is tentatively confirmed.

Implications

Based on the preliminary findings during the pilot program for MRI scanning of patients with MR conditional CIED, the program has been consistently and safely applied to the aggregate population with no detrimental effects to CIED function. These findings will support the recommendation of adoption of the policy and program for MRI of MR conditional pacemakers within the organization. The overarching implication of this program will be access for a diagnostic modality, MRI, to an aggregate population of patients who have previously been denied this option. Over the course of 10 months, 34 scans were performed at the organization. This is significant when considering that despite the introduction of MR conditional CIED in 2011, many organizations continue to deny MRI as a diagnostic modality for these patients. Sabzervari et al. (2017) surveyed hospitals in England regarding MRI services offered to patients with CIED and found that although 98% of respondents were aware of the new technology, only 46% offered MRI to patients with MR conditional devices, and only three of those centers performed greater than 20 scans per year.

Recommendations

Adoption of the policy and pilot program as practice within the organization is recommended. Based on observations during the pilot program and scholars demonstrating new and evolving evidence, recommendations for changes to the program can be identified. The Iowa model used in the development of the pilot program requires iterative feedback

and evaluation (Titler et al, 2001). Therefore, recommendations regarding changes to the current program, increasing the scope of the project, and areas of future study have been identified for discussion.

Current Program

The original protocol was designed for scheduled, prescreened patients. As this project has developed and providers have learned that it is now possible to safely obtain MRI on some pacemaker patients, there have been requests for MRI in scenarios not addressed in the protocol, such as urgent and emergent MRI. Over the course of the pilot program, six (17.6%) urgent or emergent MRI scans were performed. All of these MRI scans were completed during normal business hours; therefore, this may not represent after hours requests when the trained personnel were not present to address the request. There was no mechanism in data collection to track denied emergent requests. Strom et al. (2017) reported performing 22.7% of MRI exams as emergent or urgent in their single center study.

The requests for emergent and urgent MRI scans were all based on neurological symptoms. Chalela et al. (2007) found that MRI was able to detect acute ischemic stroke more often than CT. MRI detected acute ischemic stroke 46% (CI 35-56%) in comparison to CT which detected only 10% (CI 7-14%) of acute ischemic strokes (Chalela et al., 2007). The ability to detect acute ischemic stroke went up for MRI in those patients scanned within 3 hours of symptom onset with MRI detecting 46% and CT 7% (Chalela et al., 2007). Despite the importance of rapid diagnosis and treatment for stroke symptoms, Nazarian et al. (2016) found that among patients with neurological

stroke symptoms, 44% of patients without CIED were likely to have MRI imaging versus 1% of patients with ICD implants.

The request for emergent MRI services on patients with MR conditional pacemakers has implications for staffing, finance, and scheduling. Although there seems to be no reason that the protocol could not be applied on an emergent basis contingent upon appropriate screening, if emergent/urgent MRI is to be offered to this aggregate population, it would require a larger staff training effort with on-call responsibilities, scheduling, and wages. Further analysis of return on investment from a clinical impact and financial perspective would be needed. In discussion of emergent and urgent MRI of CIED, Gimbel (2017) opined, “a well-honed care pathway for such patients needs to be developed and maintained; a scattershot approach to care is likely a recipe for confusion and misadventure” (para. 5).

Increasing Scope

The pilot program for this project addressed MRI of MR conditional CIED. While there was literature supporting the safety of MRI in patients with non-MR conditional technology, referred to as legacy devices, prior to beginning the pilot program, a landmark study was published during the project. Russo et al. (2017) reported the findings of the Magna Safe Registry in which 1000 patients with legacy pacemakers and 500 patients with legacy ICDs underwent clinically indicated, non-thoracic MRI scans after appropriate screening, device reprogramming, and monitoring protocol. There was one power on reset requiring device replacement, six episodes of arrhythmia, and six partial electrical resets (Russo et al., 2017). Device setting changes occurred; however,

did not meet criteria for clinical significance (Russo et al., 2017). Hence, increasing the evidence that legacy devices can be safely scanned with use of an evidence-based protocol. A Canadian Consensus Statement places the incidence of serious adverse or life-threatening events from MRI of legacy devices at <1% (Verma et al., 2014).

Expanding the scope of the pilot program to include legacy devices would increase access to MRI as a diagnostic modality. However, the Centers for Medicare and Medicaid Services (CMS) do not provide reimbursement for this procedure which remains an off-label use according to the FDA (Kramer & Kesselheim, 2017). According to Kramer and Kesselheim (2017), this reimbursement decision was amended by CMS to allow coverage for those with legacy devices that undergo MRI through participation in a prospective registry. Private insurers generally reflect CMS practices. Therefore, patients with legacy devices must undergo MRI at registry centers in order to insurance to provide reimbursement. The staffing and monitoring burden for the maintenance of a registry makes expansion of the scope of the program a significant clinical and administrative decision to be addressed over time.

Strengths and limitations of the project

This project was limited by the small number of scans performed. The sample group was a convenience sample comprised of all patients with MR conditional CIED referred to the single academic medical center for MRI. Thus, this cohort had the potential to have referral bias. There was no control group for comparison as this was a quality improvement evaluation and not a research trial.

Future Study

Throughout the course of the pilot program for MRI of MR conditional pacemaker patients, additional questions arose regarding this procedure and aggregate population. A literature review identified gaps in knowledge such as determination of exam utility and outcomes, device implant decisions, patient experience and perceptions, and special circumstances such as the use of general anesthesia and sedation. These identified gaps in knowledge are discussed for future study.

Exam Utility

As MRI of CIED increases in practice, there remains risks attendant to the procedure and the supervisory burden for the exam. A mechanism to monitor the utility of MRI exam should be considered. Strom et al. (2017) developed criteria for determination of utility of MRI studies. The criteria included interpretable study, identification of new diagnosis, confirmation of diagnosis, and/or change in treatment plan based on MRI results (Strom et al., 2017). If the MRI exam was interpretable and one other criterion was met, the MRI was judged useful (Strom et al., 2017). However, this does not translate to a demonstrable change in long term outcomes and more study is needed to address this gap in knowledge.

Determinants of Type of Device Implanted

As more evidence is published regarding the safety of MRI of legacy pacemakers there is increasing discussion regarding clinician selection of which type of device to implant going forward. The new MR conditional technology is more expensive, approximately \$500 per system; however, even though considered safe the risk of off

label scanning in non-conditional devices is not zero and it is not reimbursed by CMS (Gimbel, 2017). Gimbel (2017) reports there are no head to head comparisons of MR conditional versus non-MR conditional devices exist. More evidence is needed in order to guide patients to the appropriate device while considering safety, access, and expense.

Patient Experiences and Perceptions

Anecdotally, many patients with CIED who presented for MRI described anxiety and fear for the safety of the procedure and potential effects on device function. In a grounded study of pacemaker patients, Malm and Hallberg (2006) found themes of imposing restrictions which were based in lack of understanding regarding what was safe for the device in daily life scenarios. Electromagnetic fields were specifically mentioned as technology likely to pose a threat to the appropriate function of the pacemaker (Malm & Hallberg, 2006). Many subjects reported feelings of unease in proximity to such technologies (Malm & Hallberg, 2006). MR conditional devices are new technology with FDA approval occurring in 2011 (FDA, 2011). Patients may have peers with older technology that are not able to have MRI and this could cause confusion and concern for the safety of the test.

The MRI examination may be anxiety producing in many patients. Van Minde, Klaming, and Weda (2014) reported MRI associated anxiety due to claustrophobia, loud noises, table movement/vibration, and duration of the test. These scholars found the highest level of anxiety existed at the beginning of the exam (Van Minde et al., 2014).

Therefore, education and reassurance regarding the safety precautions for MRI testing will be needed for informed consent and decreased anxiety. The development of

educational materials for this aggregate population would be ideal. There is no literature that addresses MRI and pacemaker anxiety and this identified gap in literature would require further study in order to understand and develop interventions for this phenomenon.

Sedation and Anesthesia for MRI of Pacemaker Patients

During the pilot study, there were two requests for MRI with general anesthesia or sedation. These requests were declined after review of literature and manufacturer guidelines. Guidelines for MRI of MR conditional devices require that manufacturer recommendations be followed (ACR, 2013). The guidelines state that monitoring staff must have visual and verbal contact with the patient for the entire exam and this is not possible in the setting of general anesthesia or any sedation other than light (Medtronic, 2013). Manufacturer technical support services were contacted and the use of general anesthesia was reported as off label use. Review of the literature revealed no studies with evidence to support this practice and therefore a gap in knowledge has been identified for future study.

Summary

The data was analyzed using SPSS software. Descriptive data was used to describe the population who were included in the pilot program. Program fidelity was reported as frequency data. A paired t-test was used to evaluate for differences in lead impedance and pacing threshold. This revealed no statistically significant changes between pre and post MRI. Patient-reported symptoms were examined using the McNemar chi square test. This test revealed no significant difference. These findings

were used to endorse the adoption of the pilot program as policy for the organization.

Based on experiences in the pilot program, consideration of additional program policy for urgent/emergent MRI scanning and increasing scope to include legacy devices were recommended. Areas of future study were discovered throughout the course of the pilot and include exam utility, device selection, patient anxiety, and MRI in the setting of anesthesia and sedation.

In the final section a dissemination plan and evaluation of learning throughout the course of the project will be discussed.

Section 5: Dissemination Plan

Dissemination

Ousley et al. (2010) reported that access to evidence is one of the early steps in translation of evidence to practice. Walsh (2010) found that respondents to a survey regarding use of evidence-based practice (EBP) indicated that the primary opportunity for EBP arose from the availability of evidence. Hence, it is important for clear and concise dissemination of results from research endeavors. Forsyth et al. (2010) discussed the increasing importance of dissemination of EBP initiatives in order to replicate and apply evidence to improve health care quality. Forsyth et al. opined that dissemination is where the true benefit of practice change initiatives takes place. As a scholar-practitioner and nurse leader, it is important to both disseminate findings and to be aware of dissemination of the findings of others in order to lead translation of evidence into practice. Ultimately, dissemination of evidence should support and promote innovation in practice for high quality care through the contributions of engaged providers. Inadequate dissemination and adoption of EBP creates a chasm between best practices and actual care.

I have selected a poster presentation at my organization's annual nursing quality symposium as the format and forum approach for dissemination of my project findings. See Appendix D for poster design. I chose a poster presentation for many of the reasons found outlined in Forsyth et al. (2010) including less formal, no time restrictions, and the ability to edit based on audience. Forsyth et al. reported the major benefit of poster presentations is "[p]rovision of a less stressful and inviting environment to disseminate EBP project information is essential to ensure active involvement of clinically-based

health care professionals” (p. 16). This promotes dissemination of evidence in a format that could be less intimidating than others, which may increase dissemination efforts.

The information presented in a poster can be customized to the audience. The added benefit of the poster presentation was described by Hand (2010) in which the poster only serves to attract interest; with the average time spent reading a poster being 3-5 minutes, it is then up to the presenter to demonstrate in-depth knowledge of the topic that can cater to the interests of the individual engaged. For example, the points I might choose to discuss with an EP nurse practitioner regarding MRI protocols for pacemaker patients would differ from the information I might share with a primary care provider who might be considering ordering this diagnostic modality for a patient in this aggregate population.

Analysis of Self

Over the course of my doctoral studies and project, I found a significant change in how I approached topics, such as leadership, advanced practice, QI, health outcomes, and health policy. The future benefits of my doctoral degree and career advancement are also included in the analysis of myself.

Leadership

Improvement in leadership skills was one of the main goals I identified for the doctoral capstone project. Through the practicum experience and DNP project process, I have increased my understanding of organizational and systems issues that can impact health care.

There are many types of intelligence that comprise effective leadership. These include emotional, social, and political. Emotional intelligence involves self-awareness and self-management to manage interactions with others (Jones, 2016). Political intelligence requires astuteness in adjusting to situational needs in a way that can influence others (Jones, 2016). Social intelligence demonstrates the ability to create positive feelings in those whose support is needed (Jones, 2016). The opportunities afforded by the doctoral project experience have allowed me to develop in all three intelligence arenas.

Throughout the course of my project, I found it necessary to work collaboratively with an array of interdisciplinary professionals, such as radiology, internal medicine, information technology, administration, billing, and scheduling. Additionally, the nursing department and internal medicine department shared oversight of my project activities as a DNP student. I gained political intelligence as I worked with these departments to meet organizational requirements to plan and implement a change in the practice paradigm. I feel that I have developed leadership skills that will prove useful moving forward in a leadership role as scholar-practitioner.

I believe I am prepared to be a leader in health care issues. My doctoral project experience has taught me to look to the literature to understand problems, discuss topics with other team members to understand their perspective, and engage in a meaningful way to become a change agent. The DNP experience has allowed me to broaden my knowledge base and approach complex issues with an understanding of the system as a whole. When I first began the doctoral project, my approach to leadership focused much

more on the immediate circumstances and needs. I was more managerial in my approach with attention to organization and established policy. Now, as a leader, I am able to discuss ideas, impact, and engagement associated with practice change.

Advanced Nursing Practice

There are eight core competencies that are considered essential for advanced practice nursing at the doctoral (DNP) level. These include scientific underpinnings, organizational and systems leadership, clinical scholarship and EBP, information systems and technology, policy and advocacy, interprofessional collaboration, population health, and advanced practice nursing (AACN, 2006). My initial impression of the DNP essential competencies was that not all were necessarily applicable to my career goals as an acute care nurse practitioner which I felt was largely clinical in focus. However, over the course of my practicum experiences I experienced how the core competencies dovetail together to impact a much more comprehensive approach to advanced nursing practice.

My project for MRI of patients with CIEDs provides an example of the use of each DNP essential in order to achieve the desired outcome. I used the scientific underpinnings of nursing for understanding the theories supporting my project. I used leadership and systems thinking to develop a plan to analyze the pilot program. I used the literature review to determine best practices currently applied to the problem. An understanding of technology and information systems was used to develop templates for documentation and data collection, as well as development of the ability to understand the computerized technology used to manage cardiac devices. Policy writing became a piece of the project as the actual protocol was written to guide the pilot program. The

project was designed to improve access to care for the aggregate population of patients with cardiac devices. All was done within the advance practice nursing role of the acute care nurse practitioner. If one project can touch on each essential core competency, so must the ongoing daily practice of the doctorally prepared advanced practice nurse.

Promoting Quality Improvement

My practicum experience and capstone project were based on the premise of QI, and I became adept in approaching QI issues with the use of the Donabedian framework for QI. The Donabedian framework for quality examines structure, process, and outcomes. Interactions among providers and patients make up process (Donabedian, 1978). Structure refers to the environment, equipment, and resources with which the providers work (Donabedian, 1978). The actual change in the current and future health for a patient/population based on process and structure is the outcome (Donabedian, 1978).

In order to achieve the identified quality outcomes, I used information systems and technology to enhance implementation of structure component of quality. Documentation templates were created to ensure standardized data collection of key elements, appropriate patient records were maintained, and billing practices were supported. I also worked collaboratively with the information technology team to revise the MRI computerized order entry and create a best practice advisory to assist the provider in placing the correct order for the correct patient scenario to trigger application of the protocol. Additionally, interrogation of cardiac implantable devices was performed

and work was started to integrate this technology with the current EHR to create seamless transfer of patient information.

As a result of these efforts for QI and the use of information technology, I became more adept in recognizing ways to leverage information technology for the use of improved patient outcomes. Once information technology is used and understood, there are a multitude of options to leverage the technology for improvement of outcomes. This has been a change in my perception from using the EHR as a tool for order entry and documentation to a systems level application designed to impact aggregate populations and health care in general.

Improving Health Outcomes

I was able to serve as a change agent for a new practice which will affect the outcomes of patient care through increased access to important diagnostic modalities for an aggregate population. One way that I was able to serve as a change agent was through increased knowledge in pacemaker design and function and how this technology interacted with the design and function of MRI technology. As part of my practicum experience, I immersed myself in pacemaker clinics to observe and understand device function and its impact on patients. This expertise allowed me to have knowledgeable discussions in collaboration with ordering providers regarding practices for MRI on pacemaker patients. The relationships I was able to develop with other providers as a result of this collaboration increased access to a diagnostic modality for pacemaker patients. The initial impact on patient outcome was seen with appropriate device function post MRI scan; however, future impact on patient outcomes may come to fruition much

later in the continuum of care as early detection of conditions have potential impact on treatment options for many patients.

Informing Health Care Policy

As a part of the practicum experience and DNP project, I was the primary author for an organizational policy regarding MRI of patients with MR conditional CEID. This policy was designed to provide a framework for the application of an evidence-based protocol ensuring patient safety, efficacy, and access. This policy was written in collaboration with other disciplines and I learned to appreciate the perspective that other stakeholders bring to policy formation.

The largest learning curve for me in the arena of policy was the ability to analyze the financial and business side of policy creation. Performing a financial analysis and demonstrating the potential impact of the practice change was most challenging. An examination and understanding of the budget allowed for planning in which activities can be prioritized to advance the goals of the mission of the program allowing for both effectiveness and efficiency. One challenge of the proposed budget was silo budgeting in which budgets were managed independently within the overall health system (U.S. National Library of Medicine, 2008). The proposed program was a collaborative effort between radiology and electrophysiology; however, each department had a separate budget. Thus, I found this program had a positive budget impact for one department and a negative budget impact for the other.

Future Benefits

My knowledge and core competencies were expanded through the practicum experience and DNP project. Another benefit of the practicum experience was derived from placing me in the position to showcase the education and skills of the DNP prepared nurse practitioner. As I worked through the DNP curriculum, I was repeatedly placed in front of key stakeholders such as nursing administration and medical directors. These opportunities allowed me to demonstrate the education, skills, and impact on outcomes that the DNP prepared nurse practitioner can offer. This led to a re-evaluation of roles. I believe there will be long term benefit to the overall role of advanced practice nurses within the organization based on interactions associated with this DNP project and its dissemination.

Challenges and Insights

The greatest challenge was the administrative task of project approval and dissemination. While I am fortunate to work at a Magnet status academic health center with a culture that fosters nursing innovation and research, I found that clinical practice at one organization with academic undertaking at another was not seamless. I also found that working as a nurse practitioner in the internal medicine department while my academic endeavors were governed by the nursing education department created communication silos that were often difficult to overcome. These experiences were educational and allowed me to better understand the healthcare system. Additionally, it was insightful regarding the barriers that result in increased time to implement new

evidence into practice. This phenomenon was not unique to my clinical and academic institutions and is addressed by the IOM and Mannatt report.

The Institute of Medicine (2010) discussed the future of nursing and recommended nurses practice to the fullest extent of their education, achieve higher levels of education with seamless progression, be full partners on the healthcare team, and improve policy, data collection, and infrastructure. AACN (2016) created the Manatt report to address changes in academic nursing to foster the goals put forth by the IOM. In order to achieve the overarching goal of embracing a new vision for academic nursing, the following recommendations were made for academic nursing and health centers: 1. Enhance the clinical practice of academic nursing 2. Partner in preparing future nurses 3. Implementation of accountable care 4. Integration of nursing research into clinical practice and 6. Create an advocacy agenda.

Clinical and translational research will be increasingly transdisciplinary as healthcare evolves; therefore, creating a culture of interdepartmental, academic, and clinical communication and cooperation will be integral to the future progress of innovation in healthcare.

Summary

Although historically there have been risks associated with MRI of patients with pacemakers, recent technological advancements, evidence from randomized controlled trials and prospective studies, and expert opinion have begun to change the practice paradigm and the presence of a pacemaker is no longer an absolute contraindication to MRI as a diagnostic tool. The implementation of an evidence-based, nurse practitioner

administered guideline provided the aggregate MR-conditional pacemaker patient population with increased access to MRI as a diagnostic tool. The Iowa Model and Donabedian Framework were used to apply MRI and pacemaker principles and evidence from clinical trials to the local context. This quality improvement project was an evaluation of the evidence-based protocol clinical outcomes using descriptive statistics, program fidelity, and clinical indicators to support a formative evaluation. Data collected via chart review included device type, MRI site, adherence to manufacturer recommendations, pre/post device interrogation parameters, and patient reported symptoms. These data were analyzed and revealed no statistically significant changes to pacemaker device function or patient-reported symptoms after MRI. The protocol was deemed safe and recommended for full adoption of the protocol. This project addressed a gap in practice for an aggregate population and supported a change in the practice paradigm that will serve to increase access to the diagnostic modality of MRI. There are plans in place to disseminate project findings via poster presentation at the organizational annual quality symposium. This project provided learning experiences in all of the AACN doctoral essentials and contributed to my growth as a clinician and scholar.

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Policy and Procedure Manual

MRI Scanning for Patients with MR Conditional Pacemaker

SUBJECT: MRI Scanning for patients with MR conditional devices

PURPOSE: To assure consistently safe MRI scanning of MR conditional devices.

DEFINITION: Trained personnel:

- A. ARNP/PA trained in MR conditional device screening, management, and possible complications with the skill to perform ACLS including CPR, arrhythmia recognition, defibrillation, and transcutaneous pacing.
- B. MRI technicians trained in MR conditional devices including screening and possible complications.
- C. MR conditional: Under specific conditions there are no known hazards or risks in an MRI environment.

POLICY:

- A. MRI scanning of MR conditional devices must be a collaborative effort between cardiology and radiology.
- B. MRI scanning of MR conditional devices must be performed using a standardized protocol following the appropriate conditions of use and manufacturer recommendations.
- C. Trained personnel:
 1. Device interrogation and reprogramming will be performed by a device trained LIP with ACLS training who will remain with the patient throughout the scan until the device has been programmed back to original settings and interrogation demonstrates device is properly functioning.
 2. MRI scan will be performed by MR conditional trained MR technician.

EQUIPMENT:

- A. MRI 1.5 Tesla

- B. Device programming system (Biotronik, Medtronic, Boston Scientific)
- C. MR safe cardiac and oxygen saturation monitoring equipment
- D. Emergency equipment with capability to externally pace and defibrillate

PROCEDURE:

- A. Schedule patient for MRI and coordinate with EP ARNP/PA.
- B. Screen for complete MR conditional system and confirm with manufacturer.
 - 1. Biotronik: 1-800-547-0394
 - 2. Medtronic: 1-800-925-3368
 - 3. Boston Scientific: 1-800-227-3422
- C. Obtain informed consent.
- D. Confirm patient identity.
- E. Confirm MRI screening has been performed.
- F. Perform device interrogation and document battery life, lead impedance, sensing, and thresholds.
- G. Confirm and document all manufacturer recommendations for device are met.
 - 1. Biotronik:
 - a. Cardiology:
 - 1. Complete MR conditional device.
 - 2. Patient is afebrile.
 - 3. Patient height is at least 1.4 meters.
 - 4. The device system has been implanted at least 6 weeks.
 - 5. The device system is implanted in the chest area.
 - 6. Pacing threshold is not above 2.0 V at 0.4 ms.
 - 7. Lead impedance between 200-1500 ohms.
 - 8. Device programmed to MRI mode immediately prior to scan.
 - b. Radiology:
 - D. MRI system is closed tube, cylindrical magnets, with a static field strength of 1.5 T.
 - E. Slew rate must not exceed 200 T/m/s.
 - F. HF field generated solely by the body coil built into the MRI scanner with no additional local emitting coils.

- G. MRI performed with patient in dorsal position only.
- H. Overall accumulative time required for imaging must not exceed 30 minutes.
- I. Specific absorption rate for the whole body must not exceed 2.0 W/kg.

2. Medtronic:

a. Cardiology:

- 1. Patient implanted with MR conditional device. Only patients with a complete MR conditional system may undergo MRI.
- 2. Pacemaker and leads have been implanted for 6 weeks.
- 3. Atrial and RV thresholds do not exceed 2.0 at 0.4 ms.
- 4. Confirm there are no lead extenders/adaptors, no abandoned leads, or leads that are not electrically intact.
- 5. Device programmed with SureScan mode on prior to entering magnet.
- 6. Patients with ICD or CRT receive no tachy-therapies and no CRT support in SureScan mode.

b. Radiology:

- 1. Horizontal field, cylindrical bore, clinical system for hydrogen proton imaging.
- 2. MRI power 1.5 T, normal operating mode.
- 3. Whole body averaged specific absorption rate (SAR) must be ≤ 2.0 W/kg
- 4. Head SAR must be ≤ 3.2 W/kg
- 5. Maximum spatial gradient ≤ 20 T/m
- 6. Gradient systems with a maximum gradient slew rate performance per axis of ≤ 200 T/m/s

3. Boston Scientific:

a. Cardiology:

- 1. Patient implanted with MR conditional device.
- 2. Device has been implanted for a minimum of 6 weeks without lead or other surgical revision within the 6-week time period.
- 3. Generator implantation in the left or right pectoral region.
- 4. No abandoned leads, lead adapters, or extenders.
- 5. No evidence of fractured lead or compromised generator/lead integrity, damage to the generator seal plug or rings.
- 6. Pacing threshold $\leq 2.0V$ in pace-dependent patients.
- 7. Bipolar pacing operation or pacing OFF.
- 8. Patient is afebrile.

9. Pulse generator programmed to MRI protection mode during scan.

b. Radiology:

1. Magnet strength 1.5 T with radiofrequency of approximately 64 MHz, and spatial gradient no greater than 50 T/m over pacing system.
 2. Horizontal, H proton, closed bore scanners only.
 3. Specific Absorption Rate (SAR) limits: whole body averaged ≤ 4.0 W/kg, Head ≤ 3.2 W/kg.
 4. Maximum specified gradient slew rate ≤ 200 T/m/s per axis.
 5. No local transmit only coils or local transmit/receive coils placed directly over the pacing system. The use of receive only coils is not restricted.
 6. Patient in supine or prone position only.
- H. Program the device to MRI scan mode.
- J. Connect patient to telemetry and SpO₂ monitor for continuous monitoring until baseline or clinically appropriate device settings have been restored.
- J. Perform MRI scan as ordered with 1.5 T MRI scanner adhering to manufacturer specifications.
- K. Assess patient for any symptoms such as warmth/heating or vibration at the pacemaker site, hemodynamic changes, lightheadedness, dizziness, shortness of breath, or palpitations.
- L. Upon completion of MRI scan, reprogram device to original settings.
- M. Perform device interrogation including battery life, lead impedance, sensing, and thresholds. If significant changes (i.e. threshold change of greater than 0.5 V at 0.4 ms) are noted document and consult electrophysiologist.
- N. All documentation should be completed in MRI/Pacemaker documentation template in EPIC.

RELATED STANDARDS:

American Heart Association
American College of Radiology

REFERENCES:

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- Medtronic. (2016). MRI Sure Scan Systems: Patient scanning process. Retrieved from <http://www.medtronic.com/mrisurescan-us/pdf/surescan-systems-patient-scanning-process.pdf>

Date Created: 7/15/16

Appendix B: Sample of organizational MRI order prior to change in practice

MRI BRAIN W/WO CONTRAST (70553) ✓ Acc

Starting: 1/7/2016 Today Tomorrow At: 1518 🕒

Starting: Today 1518 Until Specified Show Additional O

Scheduled Times: [Show Schedule](#)

Reason for Exam:

Questions:

Prompt	Answer	Comment
1. When Desired	<input type="text"/> Today Tomorrow First Available	<input type="text"/>
2. Pertinent Clinical Findings and Specific Questions to be Answered:	<input type="text"/>	
3. Is the patient able to lay flat for the duration of the MRI?	<input type="text"/>	<input type="text"/>
4. Does this patient have a pacemaker? If yes, procedure cannot be performed.	Yes No	<input type="text"/>
5. Is the patient claustrophobic?	<input type="text"/>	
6. Patient is/has diabetes mellitus, kidney disease, one kidney or kidney transplant?	<input type="text"/>	
7. If patient requires Procedural Sedation or Anesthesia, patient disposition post recovery:	Discharge to Home Return to Clinic Return to Floor Anesthesia not needed Other (specify)	
8. Patient Transport	Walk Cart Chair Isolette Portable	
9. Precautions	Oxygen Diabetic Pregnant Lactating	
10. Turn-around	Routine ASAP STAT Awaiting Discharge	
11. Does the patient require Anesthesia team?	No Anesthesia Supervised RN Sedation Anesthesia LIP	

Appendix C: Documentation Template for Data Collection

Documentation Template for MRI of MR Conditional Pacemakers**Date of Service: *****

The patient is a @AGE@ y.o. @SEX@ who is implanted with an MRI conditional pacemaker. Recommended to undergo a *** MRI by Dr. *** to evaluate ***. Informed consent was obtained for device re-programming necessary for MRI scanning.

IMPLANTED MATERIALS:

Dual/single*** Chamber Pacemaker implanted for ***

Device verified as MRI conditional with company: *** device verified as MRI conditional.

Device interrogation reveals the following:

Presenting rhythm: ***

Paced and Sensed: Atrial: ***% paced; Ventricular: ***% paced

- *Is patient pacemaker dependent?* ***

Current Programming:

Brady parameters: Pacing mode ***, lower rate limit *** beats per minute.

Measurements:

Battery:

Right atrial lead: Intrinsic P-waves measured at: *** mV. Lead Impedance: *** ohms. Pacing threshold: *** V @ 0.4 ms.

Programmed: 3.5 V @ 0.4 ms; sensitivity: 0.25 mV. Sense polarity: Bipole

Right ventricular lead: Intrinsic R-waves measured at: *** mV. Lead Impedance: *** ohms. Pacing threshold: *** V @ 0.4 ms.

Programmed: 3.5 V @ 0.4 ms; sensitivity: 0.6 mV. Sense polarity: Bipole

Left ventricular lead: Intrinsic R-waves measured at: *** mV. Lead Impedance: *** ohms. Pacing threshold: *** V @ 0.4 ms.

Programmed: 3.5 V @ 0.4 ms; sensitivity: 1.0 mV. Sense polarity: ***

Complete next section according to device manufacturer

Biotronik PRE-SCREENING CRITERIA:

The device consists only of one or more leads and a pacemaker or ICD which are each separately labeled MR conditional and can in combination constitute an MR conditional device system.

- *There are no other devices in the patient's body? *** MRI screening done? ****
 - *Abandoned leads? ****
 - *Lead adaptors? ****
 - *Lead Extensions? ****
- *Is the patient afebrile? ****
- *Is the patient's height at least 1.4 meters (140 cm or 4'7")? ****
- *Has the device been implanted at least 6 weeks? ****
- *Is the device system in the patient's chest? ****
- *Is the ascertained pacing threshold 2.0 V @0.4 ms or lower? ****
- *Is the ascertained lead impedance between 200 and 1500 ohms(Ω).? ****

Medtronic PRE-SCREENING CRITERIA:

It was verified that:

- *There are no other devices in the patient's body? *** MRI screening done? ****
 - *Abandoned leads? ****
 - *Lead adaptors? ****
 - *Lead Extensions? ****
- *SureScan pacemaker system has been implanted in the left or right pectoral region for a minimum of 6 weeks****
- *Is the ascertained pacing threshold 2.0 V @0.4 ms or lower? ****
- *Is the ascertained lead impedance between 200 and 1500 ohms(Ω).? ****

Boston Scientific PRE-SCREENING CRITERIA:

It was verified that:

- *There are no other devices in the patient's body? *** MRI screening done? ****
 - *Abandoned leads? ****
 - *Lead adaptors? ****
 - *Lead Extensions? ****
- *The pacemaker system has been implanted in the left or right pectoral region for a minimum of 6 weeks without lead or other surgical revision within the 6-week time period****
- *Is the ascertained pacing threshold 2.0 V @0.4 ms or lower? ****
- *There is no evidence of lead fracture or compromised generator/lead integrity.? ****

- *Bipolar pacing operation is OFF? ****
- *The patient is afebrile? ****
- *MRI Mode timeout used? *** time out will occur at ****

MRI SCANNER:

Verified with MRI Technologist: ***

- *Is MRI scanner is closed tube, cylindrical magnets and a static magnetic field of 1.5T? ****
- *Is the slew rate of the MRI scanner's gradient fields 200 T/m/s per axis or less? ****

Summary:

The test showed a normally functioning generator and atrial and ventricular system with appropriate lead parameters for performing an MRI. The device manufacturer recommendations have been met. The device has been reprogrammed to MRI mode for scan.

The patient was continuously monitored throughout the scan with telemetry and oxygen saturation and remained hemodynamically stable. The patient reported***symptoms.

Post MRI Scan:

- The device was reprogrammed from MRI mode to documented pre-scan programming? ***
- Battery: ***
- Lead impedance remained 200 and 1500 ohms(Ω).? ***
- Threshold testing revealed no changes > 0.5 Volts from pre-screening parameters? ***

Appendix D: Project Poster for Dissemination

Evaluation of Protocol for MRI of MR Conditional Cardiac Devices

Shelly McGurk, DNP, ARNP, ACNP-BC

