**Remote Programming of Cardiac Implantable Electronic Devices: A Novel Approach to Program Cardiac Devices for Magnetic Resonance Imaging**

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**Introduction**

Magnetic resonance imaging (MRI) is a powerful diagnostic imaging tool which has rapidly expanded over the last 2 decades. Each year over 60 million MRI scans are performed worldwide(1). However, the strong magnetic fields involved in MRI scanning obviates the use of ferromagnetic equipment and has been particularly challenging in patients with cardiac implantable electronic devices (CIEDs). With more than 1 million new CIED implants in the United States each year(2). MR imaging in this population remains a logistical problem in most hospital systems.

As recently as the early 2000s, patients with CIEDs were unable to safely complete MRI scans due to concerns with asynchronous pacing, movement of the implantable device by the strong electromagnetic field, and excessive heating of the lead tips(3). In the past 20 years, technology has improved to enable MRI scanning for individuals with a CIED. Nazarian et al.(4) found that patients with select implantable pacemaker and defibrillator systems, and under appropriate precautions, can safely participate in MRI scans. MRI-conditional devices were subsequently approved for use within specific MRI environments (5). However, physicians need to remain mindful of the specific static magnetic field, gradient magnetic fields, radiofrequency energy present in the MRI machine(5).

The MRI-conditional devices are proven to be safe, however they must first be temporarily reprogrammed to an ‘MRI-safe’ mode(6). Traditionally, this required an MRI technician or electrophysiology certified health care professional to be on-site before and after the MRI scan. Remote monitoring of CIEDs has been around since the 2000s and has helped physicians to closely monitor patient’s heart rhythms. One of the major CIED vendors, Medtronic, updated its remote monitoring system CareLink to allow remote CIED reprogramming(7). This new technology can revolutionize the way cardiac implantable devices are monitored and reprogrammed.

There is limited literature on the safety of remote reprogramming, especially in the emergent setting. This study aims to delineate the efficacy and safety of remote reprogramming of MRI-conditional cardiac devices. The authors hypothesized that remote programming is similar in safety and efficacy as in-person programming for patients with MRI-conditional CIEDs.

**Methods**

This was a single center, observational study looking primarily at safety of remote reprogramming. The study was approved by the local institutional review board with waiver of patient consent due to the observational nature. We included all consecutive patients from 01/01/2020 to 08/31/2021 presenting for an MRI scan with an MRI conditional Medtronic CIED.

The MRI department informed the device representative regarding patients undergoing an MRI scan with MRI conditional devices. On patient’s arrival, an MRI technician started the session by contacting the remote operator and placing the programmer wand of a 2090 Medtronic programmer on the patient’s device. The Medtronic programmer had a remote-control software installed on it. The remote operator after logging into a remote access software (BomgarTM) from a remote device provided an access code to the MRI technician that was generated by the software. Once the access code was entered into the 2090 programmer by the technician, the remote operator was able to obtain control of the programmer to interrogate and program the device as needed (Figure 1). The device was programmed to a prespecified MRI-safe mode using the Medtronic MRI SureScanTM system before the MRI scan(8). Pacemakers were switched to a VOO, AOO or DOO mode based on the type of the device and reason for device implantation. Tachyarrhythmias therapy and sensing function of implantable cardioverter defibrillator (ICDs) were turned off to avoid inadvertent shocks during the scan. To maintain patient safety an external defibrillator was available by patient’s bedside for the period of the scan. After the completion of the scan, the device was reprogrammed to the patient’s baseline settings and a programming report was generated to be uploaded to the patient’s electronic medical record.

The following primary outcomes were measured:

1. Percentage of successful completion of remote device reprogramming.
2. Number of patients that required traditional non-remote device reprogramming.
3. Number of patients that developed symptoms during device reprogramming
4. Number of patients requiring changes from their baseline device settings after the MRI scan.

The following prespecified subgroups were analyzed:

1. Stat vs routine scans as determined by the ordering physician.
2. Urgent vs non-urgent scans as determined by the device representative. Scans were determined as urgent if ordered ‘stat’ or if the device representative was not informed in advance regarding a patient with a CIED arriving for an MRI scan, such as for patients that the MRI department was unaware had a CIED.
3. Area of body scanned
4. Pacemaker dependent or not dependent.
5. Location of patient - inpatient versus outpatient.

We also measured the average time to travel for the device representative to the MRI suite. This was obtained by calculating the time required by each device representative to travel from their home to the MRI suite as known historically for in-person device programming.

Exclusion criteria:

1. Non-MRI conditional CIEDs
2. Non-Medtronic CIEDs

**Results**

A total 209 RP sessions were performed for MRI scans, including 51 urgent scans and 22 stat orders. Mean age of the patients in the study was 72+/-13 years. Characteristics of the patients are illustrated in table 1. None of the remote programming sessions demonstrated any issues with connectivity or device reprogramming. These results were consistent across subgroups. No patient symptoms were observed during remote reprogramming. No patient required any changes to the baseline device settings after the MRI scan. No patient required rescheduling of MRI scan related to any problem with remote connection or reprogramming. The estimated time saved per scan as calculated by measuring the device representative to travel to the MRI suite was 28 +/-10 minutes.

**Discussion**

Our single-center observational study of remote reprogramming of CIED’s using the RemoteControl™ (Medtronic) technology for MRI scans found no issues with establishing and maintaining connection of the patient’s device to the remote programmer and performing the required programming of the device. These results were consistent independent of urgency of the scan, pacer dependency of the patient, type of device being programmed, part of the body being scanned and location of the scan (inpatient vs outpatient).

Remote monitoring (RM) of CIEDs in comparison with traditional in-person evaluation has been studied extensively and has been shown to be a safe and effective strategy. It has shown to reduce the number of shocks, prolong the device battery life and improve survival(9-11). Based on these studies, Heart Rhythm Society Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices recommended (Class I) regular remote monitoring and interrogation of CIED’s in addition to annual in-person evaluation(12). However, studies evaluating RP of CIEDs have been limited. In a previous trial by Kloosterman et al (13), RP of CIED’s using the RemoteControl™ (Medtronic) technology during MRI scans showed results that were similar to our study. They too did not notice errors in programming the device from a remote location. In a bid to limit infectious exposure to personnel during the COVID pandemic, electrophysiologists at Ohio State University Wexner Medical Center used the same remote control technology during device implantation. In more than 20 cases, there were no flaws in programming the devices using RP(14). Compared to their study, we studied a greater number of patients and included scans requiring urgent device reprogramming and stat scans.

Though our study was limited to RP of CIED for MRI scans, it can be expanded to other settings such as the device clinic, inpatient setting and peri-operative device programming. We believe that RP will reduce unnecessary utilization of healthcare resources and manpower. This will eventually lead to reduction in healthcare costs, as it will require a smaller number of personnel for device programming, eliminate travel cost to be physically present at the location. RP of CIED’s can especially be helpful in rural areas where access to healthcare availability is limited.

Our study revealed that RP was safe and effective even when device programming is required emergently. Also, we expect it to reduce the need to reschedule MRI scans and other procedures that require device programming in case there is no device representative or other qualified personnel present by the patient’s bedside to perform the required device programming. Other strategies that are being currently studied to program CIEDs for MRI more effectively compared to the current in-person programming. One option is the Medtronic CareLink SmartSync™ Device Manager that remotely connects to the device via Bluetooth only. Hence, a qualified individual to program the device still needs to be available in the same institution and within 32 ft of the patient. The programmer received FDA approval in 2019(15). The other available option is the MRI AutoDetect feature(16). In MRI conditional devices that have this feature, the sensor within the device automatically detects a magnetic field and programs the device to an MRI safe mode. The device is reprogrammed automatically to its baseline settings after it is out of the magnetic field. This feature is still under investigation and needs large scale studies to determine its efficacy.

There are several challenges with RP of CIED’s. These include maintaining a stable connection with the device from a remote location and issues with cybersecurity. To address the first issue, we had Wi-Fi connection at the MRI suite with an ethernet connection as backup in case of problems with Wi-Fi connection. Also, there was a device representative on standby remotely to arrive at the MRI suite and program the device in case of problems with maintaining connection or programming the device remotely. In recent years, there have been some cybersecurity concerns with regards to multiple vendors(17). Specifically, in 2018, Food and Drug Administration (FDA) issued a security update about the Medtronic CareLink programmers (CareLink 2090 and CareLink Encore 29901) regarding Medtronic Software Deployment Network (SDN) which is used to obtain software updates over the internet(18), due to concerns about allowing unauthorized users to upload software onto the programmers. In-response, Medtronic temporarily disabled over the internet software updates using SDN to the programmers and allowed the updates to take place only through the USB port of the programmer until the above-mentioned cybersecurity concern was appropriately addressed. We adopted all the standard measures to maintain stringent cybersecurity such as secure passwords to log in to the programmer device, the remote device used to connect to the programmer and the remote-control software, encryption of data and randomly generated unique session codes for separate programming sessions.

**Limitations**

Our study is limited to a single center and a single CIED vendor. The estimated time saved per MRI scan was a rough estimate calculated based on approximate time taken by device representative to travel to the MRI suite. Safety and efficacy of RP need to be studied in larger patient populations, more diverse settings and with different vendors for its wide-scale utilization in clinical practice.

**Conclusion**

Remote programming of cardiac implantable electronic devices during MRI scan is a safe and effective strategy even when performed on an urgent basis. Further studies are required to assess remote programming in other clinical settings.

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