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RE: Guidelines for MRI in Patients with Cardiac Pacemakers and/or Implantable Cardioverter-Defibrillators

From: MRI Safety Pacemaker Subcommittee - Karl Vigen, PhD (chair); Aaron Field, MD, PhD; Kurt Hoffmayer, MD; Frank Korosec, PhD; Tom McKinlay, RT; Scott Reeder, MD, PhD; Meredith Welty, RT

Background: Historically, MRI of patients with cardiac pacemakers or implanted cardioverter-defibrillator (ICD) devices has been strictly contraindicated. With the increasing prevalence of implantable devices and the increasing utility and availability of MRI, there are many occasions where there is a great medical need to perform MRI in patients with an implanted cardiac device. As a result, two developments have led to the development of these guidelines for scanning patients with cardiac pacemakers / ICDs.

First, there are now several pacemakers that are FDA approved for use with MRI (MRI conditional) when used according to specific guidelines. Second, there is a substantial and growing body of evidence that patients with many devices not FDA-approved for MRI can be scanned safely under certain conditions. The purpose of this document is to outline specific guidelines and circumstances in which patients can be scanned if they have a pacemaker or ICD.

Consideration should always be given to the availability of an alternative diagnostic method, such as CT, ultrasound, or nuclear scintigraphy, even when the patient has a device approved by the FDA for MRI. However, for patients with an FDA-approved device, and when MRI is considered to be the best study to answer the clinical question, it is appropriate to perform the MRI exam. MRI can be performed safely so long as the manufacturer-specified scanning guidelines are followed. There are three approved pacemakers on the market in the United States (Revo/Advisa, Medtronic; Entovis, Biotronik). Devices from other manufacturers are expected in the near future. Guidelines for scanning patients with approved devices are detailed below. Informed consent is not required for approved devices. If an approved device must be scanned with parameters that fall outside manufacturer guidelines, it will be treated as if it is a non-approved device.

MRI remains a relative contraindication in patients with devices that have not been approved by the FDA for MRI, and these patients should only be scanned as a measure of last resort, when all other avenues have been exhausted, including invasive diagnostic procedures such as catheter-based angiography. Although there is a large body of evidence suggesting that scanning patients with non-approved devices can be performed safely, the risks are not well understood. Scanning of patients with non-approved devices as a matter of convenience or to avoid radiation from other imaging modalities is not acceptable. The decision to perform an MRI in a patient with a non-approved device requires a discussion between the patient's attending physician and the attending radiologist responsible for the imaging study. Criteria and guidelines for scanning patients with non-approved devices are detailed below. If a patient does not meet inclusion criteria, the MRI cannot be obtained. Informed consent is mandatory when scanning patients with non-approved devices. A dedicated consent form has been developed for scanning these patients, outlining potential risks specific to MRI scanning with a non-approved device.

A powerscribe template has been developed to document important information that details that the patient was scanned according to department guidelines. It is important to document this information for safety reasons (should the patient return with problems possibly related to MRI scanning), as well as billing reasons since some insurance does not reimburse for non-approved devices, but will for approved devices.

Scanning of patients with any device (approved or non-approved) must be performed with an electrophysiology device nurse present for the duration of the exam. When scanning patients with non-approved devices, an ACLS certified cardiologist must be near the MRI scanner (i.e. within 2 minutes). A physician need not be present when scanning a patient with an approved device.

Finally, no subjects with either approved or non-approved pacemakers will be imaged as part of any MRI research protocol, unless the research protocol specifically addresses all safety concerns within the IRB protocol itself.



Guidelines for UW Health-affiliated Facilities ONLY

2017 Guidelines for Scanning Patients with Non-MR Conditional Cardiac Implantable Electronic Devices (CIEDs):

1. Devices and leads must have been manufactured in 1998 or later for pacemakers and in 2000 or later for ICDs.
 - a. Device screening may be performed by the Cardiac Device Clinic Nurse, Electrophysiology (EP) Advanced Practice Provider (APP), EP fellow or EP attending.
 - b. Pacemaker-dependent patients, patients with coronary sinus leads and patients with epicardial systems are considered higher risk and are eligible on a case-by-case basis, determined by the attending electrophysiologist in consultation with the attending radiologist.
 - c. Patients with abandoned endocardial leads are not eligible - this should be confirmed by a detailed review of the operative reports and chest radiography or chest CT imaging. The use of dedicated chest radiography or chest CT imaging to determine the presence and location of abandoned leads is appropriate if needed.
 - d. A 6-week minimum time interval should typically be respected between the implant of the leads and MRI.
 - e. Patients with suboptimal pacing parameters, as determined by the attending electrophysiologist, are not eligible.
2. In every case, the risk-benefit relationship must be discussed, either in-person or via a phone-call, between the attending faculty radiologist and the referring physician.
 - a. Alternative imaging modalities (e.g., CT, US) must always be considered; the use of MRI in patients with non-FDA approved CIEDs should always be considered the diagnostic procedure of last resort.
 - b. However, care should be taken that the referring physician is not pursuing alternatives such as explanting the device system, or replacing it with an MRI-compatible model, solely for the purpose of obtaining an MRI exam; such procedures likely have a higher risk than MRI.
 - c. Imaging of patients with non-FDA approved devices is only available during weekdays (8 am-4 pm) at the UWHC (University Hospital), due to staff availability.
 - d. The decision regarding whether MRI will be performed must be made by a Radiology faculty member only (i.e., no residents or fellows).
 - e. A discussion (including informed consent) must also occur between the patient or his/her designated health care proxy, the EP fellow, EP APP or EP attending *and* the Radiology fellow or attending.
3. If an MRI procedure is deemed absolutely necessary, it must be performed as follows:
 - a. 1.5T MRI system; University Hospital only. For cardiac MRI, a 1.5T DV system (MR450w/Artist) only.
 - b. MRI system set to "Normal Operating Mode" for dB/dt *and* SAR (<2.0 W/kg body transmit, <3.2 W/kg head).
 - c. Record baseline device settings.
 - d. Set pacing device to appropriate setting:
 - i. Non-pacemaker dependent ICD patients (detections and therapies off, pacing mode based on individual case).
 - ii. Non-pacemaker dependent PM patients (pacing mode based on individual case).
 - iii. Pacemaker-dependent PM patients (asynchronous pacing mode).
 - e. The following personnel must be present, including at least one ACLS-trained staff member:
 - i. Clinical MRI Physicist (required only at the beginning of the exam).
 - ii. A Cardiac Device Clinic Nurse (ACLS trained), EP APP, EP fellow, or EP attending (i.e., personnel who is both ACLS-trained and familiar with device programming) must be present for the entire time the patient is in the MRI suite (zone 4).
 - iii. For higher-risk patients (Section 1(b) above); the EP fellow or EP attending must be present.
 - iv. If not already present in the MRI control area, the EP and Radiology attending physicians must be aware of the MRI procedure and in the University Hospital; and must be available with less than 2 minutes of response time.
 - f. The patient's blood pressure, ECG and pulse oximetry will be monitored regularly throughout the study.
4. Following the MRI scan, the device must be reprogrammed to its pre-MRI settings, and interrogated for early detection of any parameter changes. If any change occurs, routine follow-up will be scheduled as needed.



Appendix:

MRI in Patients with Conventional Pacemakers and ICDs

UW-Madison Review: March 2017

(See end note for January 2018 updates)

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In recent years, the rate at which cardiovascular implanted electronic devices (CIEDs) such as pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs) are being implanted into patients has continued to increase. Patients with these devices will often need an imaging study at some point in their lives, and MRI was traditionally considered an absolute contraindication due to the potential for device malfunction, inappropriate sensing, and lead heating due to exposure to the magnetic field gradients and RF fields used in MRI. To address the issue, device companies have begun to introduce MRI-conditional CIEDs. Pacemakers, ICDs, and Cardiac Resynchronization Therapy Devices (CRTDs) from Medtronic, Boston Scientific, Abbott (St. Jude), and Biotronik are currently FDA-approved and CE-marked (e.g. for use in Europe) with MR-conditional labeling. However, patients implanted with traditional pacemakers and ICDs may develop conditions that require MRI scans. Removal of the device and leads, and possible replacement with MR-conditional devices has been contemplated in the past, but the required surgery and lead extraction carries its own risks. As an alternative, many investigators have looked at the effects of MRI imaging on conventional pacemakers and ICDs.

Possible effects of the MRI system on pacemakers and ICD's is summarized in a review by Shinbane et al. (1). Primarily, these effects include magnetic force on the device itself, or on the magnetically-activated reed switch; malfunction due to RF interference with electronic components of the device; inappropriate sensing of cardiac rhythms due to EM interference; and the induction of current in the device leads which could lead to heating at the implanted lead tips. This last effect, in addition to tissue destruction, could cause adverse effects on measured lead impedance, sensing, and pacing capture thresholds. An accurate estimate of the rate of adverse events can be difficult to obtain; one review attributed 17 deaths worldwide after inadvertent MRI imaging of cardiac devices without patient monitoring and none with appropriate patient monitoring (2), but no sources were cited and subsequent discussion by Kanal and Gimbel questioned what role MRI actually played in the events (3) compared with other disease-related causes. Specific studies in the literature reporting adverse events are difficult to find. One case study reported reversible asystole during head imaging at 3T (4); another reported inappropriate sensing malfunction of an ICD (which inappropriately was not disabled) and increased pacing threshold (5); several additional reports have been published in the last few years (see below).

Despite the risk of adverse events, for patients that require an MRI scan, a scan following the proper precautions is likely to be safer than alternatives such as removing or replacing a non-MRI compatible device. As noted by Russo (6), the REPLACE study documented a six-month major complication rate in patients undergoing pacemaker or ICD replacement of 4% for those requiring only a device replacement and 15% for those



requiring replacement of a lead as well (7); the FDA MAUDE database reported 105 events from lead extractions between 2007-2008; and other studies have reported a 0.4% to 2% rate of major complications after lead extractions. A recent review of 17 studies of ICD replacement found a rate of major complications with a median of 4.05% (range 0.55–7.37%) and minor complications of 3.50% (range 0.36–7.37%)(8). An additional consideration is Computed Tomography (CT), often considered safe for CIEDs, has been observed to cause (rare) malfunctions in devices in the scan (radiation) field (9-11).

The review by Shinbane et al. (1) compiled data from studies documenting MRI scans performed in patients with implanted, non-MRI compatible-labeled devices, published up to 2011. In 37 studies, ranging from case reports of a single patient being scanned, to large prospective trials with up to 171 scans, a total of 832 (723 PM, 109 ICD) patients with either pacemakers or ICD's were reported to have undergone a total of 1098 MRI sessions. No serious adverse events appeared to have occurred, although changes in certain pacing parameters (i.e. small changes in pacing capture threshold, lead impedance, reprogramming of device) occurred in a number of patients. Seven subsequent studies, including a significant trial from the Hopkins group (12), include 768 (PM 502, ICD 266) patients with 972 MRI examinations, with no apparent serious adverse events (12-18).

A large multicenter, prospective clinical trial called MagnaSafe (6) was begun in 2009, with the goal of enrolling 1500 patients with either programmable pacemakers or ICDs for non-thoracic MRI. The study authors recently published results from 19 sites, including imaging 1000 exams in patients with pacemakers and 500 in patients with ICDs, in the New England Journal of Medicine in 2017 (19). Significantly, "No deaths, lead failures, losses of capture, or ventricular arrhythmias occurred during MRI." Similar to other studies, effects such as changes in battery voltage, pacing threshold, and small R-wave amplitude changes were seen in single- to double-digit percentages, with a slightly higher percentage for ICD cases. Adverse events included one inappropriately-programmed ICD that could not be interrogated after MRI, and needed replacement; and 6 cases of partial electrical reset. In addition, 6 cases of atrial fibrillation or flutter, which, based on the patients' histories, may not have been related to MRI; all eventually returned to sinus rhythm (19).

As of March 2017, 71 studies with distinct patient populations (i.e. after attempting to exclude repeats from the same institution) have been found in the peer-reviewed literature and conference proceedings, for a total of **4539** patients (3183 PM, 1323 ICD) undergoing around **5022** MRI studies (with some uncertainty in the exact numbers due to differences in reporting methods by each author). Most cases seemed to be strictly monitored with ACLS-trained personnel present, with an electrophysiologist available to reprogram the device if necessary. The most commonly reported events were occasional small changes in some detected pacing parameters (lead impedance, pacing thresholds, etc.) which did not seem to concern most study authors who mentioned them (i.e. did not lead to device or lead replacement); battery drainage and/or inaccurate event detection in a few ICD cases; and a few power-on-reset pacing inhibition that could be fixed by reprogramming after the scan. There seemed to be very few serious adverse events reported in these studies; i.e. no deaths and few long-term clinically significant adverse events.

For imaging patients with implanted devices (pacemakers and ICDs), each study typically defines its own inclusion criteria and study workflow. Most studies follow some variation of the following steps.

- Determination of the risk/benefit ratio; and appropriateness of other non-MRI imaging modalities.



- Discussion with patient, and likely informed consent obtained.
- Scanning at 1.5T only, with lowest reasonable SAR (i.e. <2.0 W/kg).
- Presence of adequate support staff, including ACLS-trained staff, backup pacing if needed, and an electrophysiologist available for device reprogramming.
- Programming of the pacemaker to a state suitable for the patient during the MRI exam (i.e. asynchronous pacing mode for pacing-dependent patients).
- Monitoring the patient throughout the scan.
- Interrogation and, if necessary, reprogramming of the device following the MRI exam.
- Follow-up, for example, at 3- or 6-months to determine device status.

Two widely-used protocols are reproduced in Figures 1 and 2. The protocol reproduced in Figure 1 is from the group at Johns Hopkins University (12,20); the one in Figure 2 is from the MagnaSafe trial (6). In both protocols, patients with ICDs who are pacemaker dependent are excluded (it seems since many ICDs do not have an asynchronous mode); otherwise, ICD patients who are not pacemaker dependent, and both types of pacemaker patients are included. Also, the Hopkins protocol excludes patients whose device was implanted before 1998 (pacemakers) or 2000 (ICDs), as the devices produced after these dates are regarded to be more EM resistant.

In February 2014, University of Wisconsin-Madison Department of Radiology, in collaboration with colleagues in the Electrophysiology Program in the Department of Medicine-Cardiovascular Division, implemented a protocol similar to the Hopkins and MagnaSafe protocols to perform MRI in patients with conventional (i.e. not labeled as MR-conditional) CIEDs. As of March 9, 2017; a total of 31 exams have been performed (15 PM, 15 ICD, 1 CRTD), with no serious complications, at a current rate of approximately 2-3 exams per month. As a comparison, since February 2012, a total of 49 patients with MR-conditional devices (43 PM, 5 ICD, 1 CRTD) have been scanned, currently at a rate of approximately 2 exams per month.

While rate of successful imaging in the literature is high, and no serious complications have been observed for patients imaged at UW-Madison, diligence in adherence to the imaging protocol is still warranted. Instances of device malfunction continue to be reported in the literature. These include power-on-resets (PORs) or partial resets of devices (19,21-23), discharges or near-discharges of ICD therapy in undetected and not properly programmed devices (24,25), and other device-related events such as oversensing (26,27). In addition, one MRI-related malfunction of an *MR-conditional* device, causing no harm to the patient, but requiring premature device replacement, has now been reported (28).

In addition, serious deliberation should be performed prior to modifying the protocol to address current exclusions. For example, some CIED patients have abandoned leads from previous devices, which are contraindicated in our current protocol. While a small number of patients have been reported to have been imaged with abandoned leads without complications (for example, 10 patients in one study (27)), phantom studies have demonstrated the potential for severe lead heating in both the abandoned leads and even nearby “MR-conditional” leads due to alterations in the local electromagnetic environment and lack of lead termination (29,30). A further consideration is that abandoned leads do not have the ability to query measurements such as pacing capture threshold following the scan which might indicated heating-related tissue damage.



January 2018 Update

In 2017, the Heart Rhythm Society published a comprehensive consensus statement on imaging of patients with devices, including MRI of patients with conventional CIEDs (31). The recommendations of the HRS consensus statement are similar to the protocols of the Hopkins group (12) and the Magnasafe study (19), described above. Among a large number of professional society which endorsed the study, the American College of Radiology is noted as one of the endorsing bodies.

In January 2018, the Hopkins group (Nazarian et al) published a compilation of their most recent results (32). In this study a total of 1509 patients (880 PM, 629 ICD) underwent a total of 2103 MRI examinations, with no clinically significant effects. The authors noted that 9 patients had devices that went into a backup mode at some point during the MRI exam (0.4%); with 1 patient needing replacement of a device with 1 month battery life remaining.

In addition, the Centers for Medicare and Medicaid Services (CMS) have proposed providing reimbursement for MRI exams for patients with conventional CIEDs. (Previously, reimbursement had only been provided for patients with devices carrying MR-conditional labeling.) Proposed guidelines state that reimbursement will be contingent on following certain procedures, which largely mirror the Magnasafe, Hopkins, and other protocols (33).

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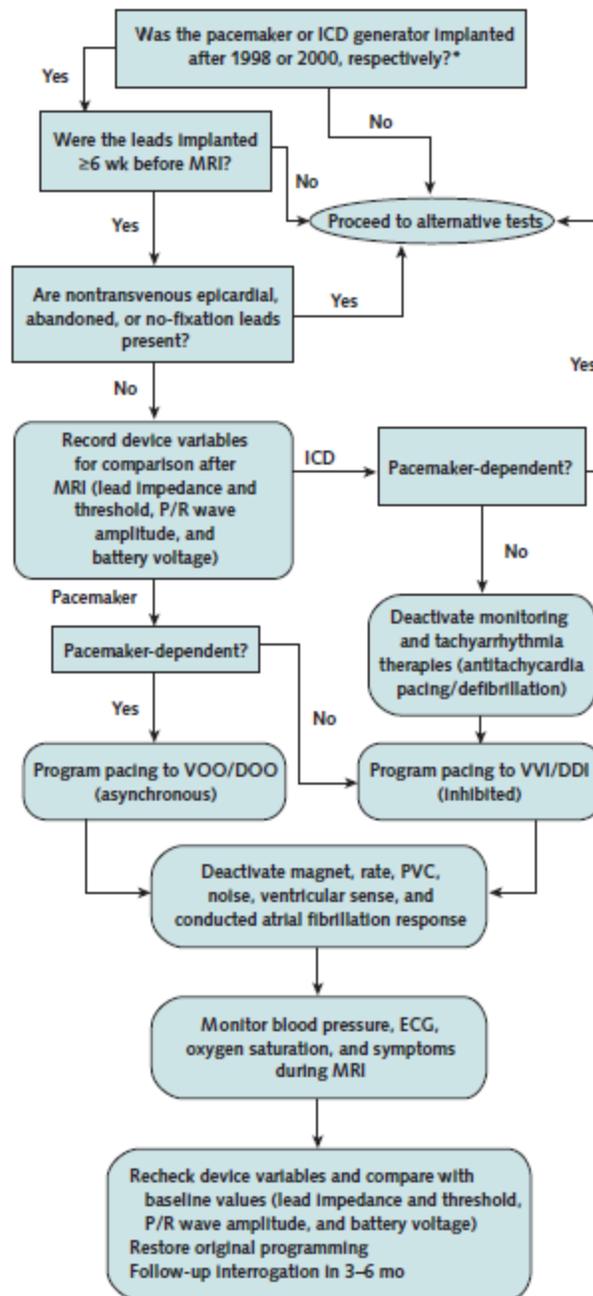
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DDI = dual-chamber inhibited pacing without atrial tracking; DOO = dual-chamber asynchronous pacing; ECG = electrocardiography; ICD = implantable cardioverter-defibrillator; MRI = magnetic resonance imaging; PVC = premature ventricular contraction; VOO = ventricular asynchronous pacing; VVI = ventricular inhibited pacing.

Figure 1: Johns Hopkins protocol for MRI of patients with pacemakers and ICDs; from Nazarian et al. (12).

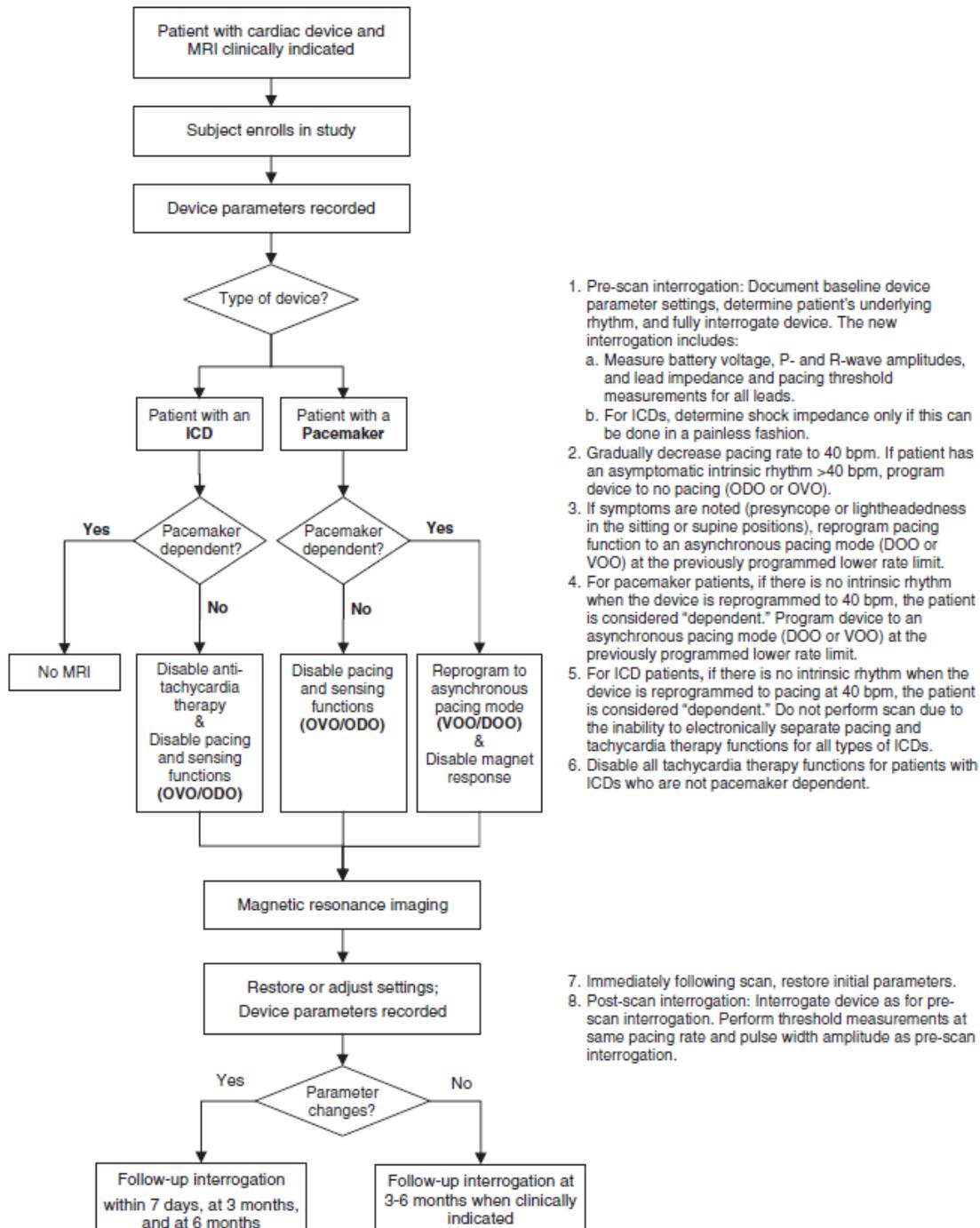


Figure 2: Protocol for MRI of a patient enrolled in the MagnaSafe study; reproduced from Russo (6).