Recent developments in MRI in patients with cardiac implanted electronic devices (CIEDs)

By Dr NG Boyle & Dr DH Do

BACKGROUND

Over 1 million pacemakers and approximately 325,000 ICDs were implanted worldwide in 2009, and this number continues to rise annually [1]. It is likely that over 50% of patients with a cardiac implanted electronic device (CIED) will have a clinical requirement for magnetic resonance imaging(MRI) following device implantation [2]. Following a number of reports in the 1990s, some of which raised the possibility of patient deaths related to MRI scans in pacemaker patients, there was widespread concern regarding the associated risks [3,4] MRI scanners use static and gradient magnetic fields, with radiofrequency energy pulses which can cause electrical malfunction of the CIED device and heating at the lead tissue interface and potential myocardial damage [5,6]. These reports resulted in most MRI departments declaring the presence of a CIED as an absolute contraindication to any form of MRI scanning, as recommended by the American Heart Association position statement in 2007 [7]. However a European position paper published in 2008 adapted a more nuanced approach, and proposed a protocol for performing MRI scans in selected patients with careful monitoring, requiring close cooperation between radiologists and cardiologists [8].

TECHNICAL ADVANCES

Given this major unmet need in large numbers of CIED patients, pacemaker companies rushed to develop so called "MR conditional" devices. Devices were modified to include fewer ferromagnetic materials, Hall switches rather than Reed switches which behave more predictably in magnetic fields, and improved internal circuit protections; leads were also remodeled to reduce their susceptibility to heating from radiofrequency energy. Clinical studies with these "MR-conditional" devices have shown virtually no clinically significant effects with MRI scanning at 1.5T either acutely or with intermediate term follow-up [9,10].

CLINICAL ADVANCES

Given the large number of patients with so called "legacy" (non-MR conditional) devices, and the major clinical need for MRI scans in these patients, several centers developed protocols for scanning these patients, similar to that proposed by the ESC position paper of 2008. One of the first large reported studies was that of Nazarian and co-workers from Johns Hopkins university reported in 2011 [11]. In a series of 555 MRI scans in 438 patients (54% pacemakers, 46% ICD, 12%CRT) with mostly non-thoracic scans (thoracic -18%), only 3 patients experienced a device "reset" to a backup mode and the study was completed in all but one patient who experienced mechanical forces on the device. While there were changes in ventricular sensing and pacing parameters which did not require reprogramming, these mostly occurred with thoracic scans; no devices required replacement.

Meanwhile, the MagnaSafe multicenter registry, led by Russo and co-workers was underway, reported in the NEJM in 2017 [12]. Starting in 2009, through 2014, they enrolled 1500 cases (1000 pacemakers, 500 ICDs) with 'non-MRI conditional' devices, undergoing nonthoracic MRI scans at 1.5 Tesla. Scans were performed according to a predefined protocol with careful monitoring and follow-up. A total of 75% of the MRIs were performed on the brain or on cervical/lumber spine. Only one ICD patient had a device malfunction requiring replacement of the device (in this patient there was a breach of protocol). In six pacemaker cases, there was a partial generator electrical reset where device settings reverted to default values; all these devices were approximately 6-10 years or post implant. Changes in lead impedance (<1% of cases), pacing threshold (<1%), battery voltage (<1% pacemakers, 4% ICDs), and P-wave (<1%) and R-wave amplitude (<1%) were observed but were all clinically insignificant. Repeat MRIs in 94 pacemaker patients and 40 ICD patients resulted in no adverse effects. There were six cases of self-terminating atrial fibrillation or flutter, mostly in patients with a prior history.

Later in 2017, the NEJM published an updated 12-year experience from Nazarian and co-workers for 1509 patients (58% pacemakers, 42% ICDs) who underwent MRIs at 1.5 T between 2003 and 2015 [13]. Scans comprised head and neck -52%, abdomen - 27% and thorax -12%. At long term follow-up (median 1 year), changes in P wave amplitude were noted in 1% of patients, atrial capture threshold in 4% and ventricular capture threshold in 4%. These changes, however, were not clinically significant and did not lead to device reprogramming or revision. In nine cases (8 pacemakers, 1 ICD) the device entered a 'reset mode', and all were reprogrammed successfully except for one pacemaker which had reached battery elective replacement indicator (ERI) prior to the scan. All of these were Medtronic devices. The scans were successfully completed in 8 of these 9 patients, except for the one patient who experienced a pulling sensation in the chest, as had been previously reported. Of note thoracic scans were performed in 12% of the patients, without evidence of any increased risk (none of the electrical reset cases occurred with thoracic scans).

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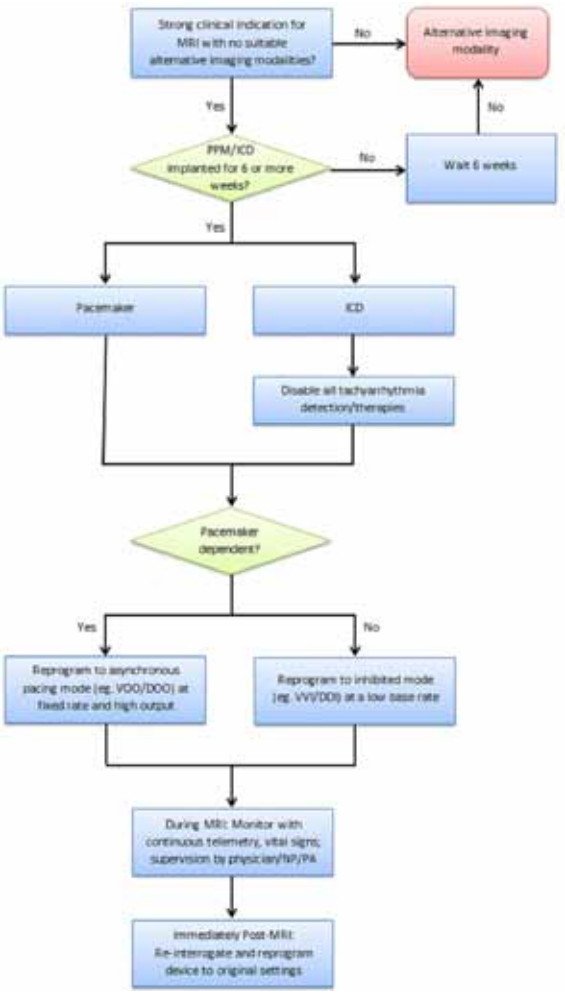

Figure 1: Algorithm for deciding optimal management for patients with non-MRI-conditional implanted devices referred for magnetic resonance imaging. Abbreviations. PPM: pacemaker, ICD: implantable cardioverter-defibrillator, NP: nurse practitioner, PA: physician assistant. From Do D. *et al.* Heart Rhythm 2018;15: 218-225

CARDIAC MRI WITH WIDEBAND IMAGING

While a growing number of centers adopted protocols for extra-thoracic MRI in patients with non-conditional devices, thoracic and cardiac MRI imaging, particularly in ICD patients, has remained an area where few were willing to venture. An important application of MRI in patients with ventricular tachycardia undergoing ablation procedures is the use of late gadolinium enhancement (LGE) to define scar zones and borders, information that is extremely valuable in procedure planning. A major drawback however, was the frequent presence of device and lead artifact obscuring the LGE images, rendering them uninterpretable in up to 44% of basal and 66% of apical ventricular segments [14]. Recent advances in MRI protocols include the development of modified "wideband" imaging sequences which eliminate hyperintensity artifacts in up to 90% of cases, enabling clinically useful image interpretation [15].

In the largest study of cardiac MRI in CIED devices, Do *et al.* reported our group's experience in 114 consecutive studies (12 pacemakers, 73 ICDs, 29 CRT-D), using a wideband sequence with LGE imaging [16]. There were no electrical resets, generator or lead failures, loss of capture in pacemaker dependent patients, new arrhythmias or patient deaths occurred. Three scans were stopped prematurely due to patient anxiety, angina chest pain and nonsustained ventricular arrhythmia prior to start of scan, respectively. Overall, 3 (3%) of studies had major artifact, while 14 (13%) had some artifact, of which 6 were mostly interpretable. Hilbert and colleagues from the Leipzig Heart Institute recently reported an 86% success in interpreting cardiac MRI using a wideband sequence, although they had proportionately more pacemakers than ICDS and more right sided implants.(17) This is similar to our overall imaging success rate of 87%. Our approach is outlined in the algorithm shown in Figure 1.

ABANDONED LEADS

Abandoned leads remain the most controversial area, with even fewer centers prepared to undertake MRIs in these patients. Particular concerns include a higher risk of RF induced lead tip heating with abandoned leads [18]. However, overwhelming clinical need for MRI, typically for brain or spinal imaging, has driven the need for scans in some patients. In an initial study reported in 2014, Friedman and colleagues at the Mayo clinic reported no serious adverse effects in 19 patients with an average of 1.6 abandoned leads [19]. The same group recently reported on a larger series of 80 patients with 90 abandoned leads who underwent a total of 97 MRI scans (Head-38, chest-22, lumber-29, limb-8), with 1.5 T scanners [20]. There was no clinical or electrical evidence of device dysfunction, arrhythmias or pain. Pre and post MRI troponin values were obtained in 40 patients with no changes, indicating no evidence of myocardial injury. The authors conclude that the risk associated with MRI wit abandoned leads appears low.

Epicardial leads have also raised concerns, particularly as almost no data are available. In one study of MRI in pediatric patients with congenital heart disease, 11 patients (mean age 9.2 years) with pacemakers (nine with epicardial leads) underwent MRI without any evidence of device malfunction or inappropriate pacing [21].

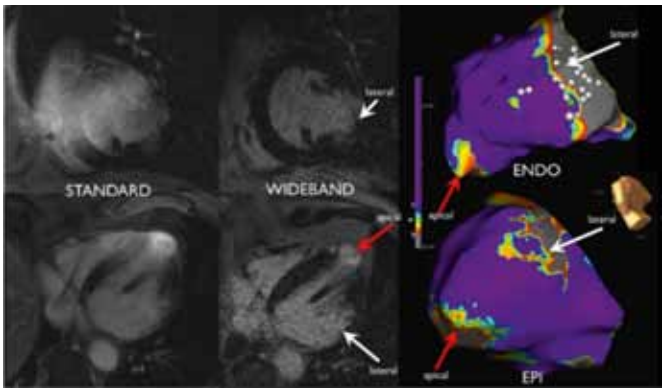

Figure 2: Standard pulse MRI with significant hyperintensivity artifact from implantable cardioverter-defibrillator (left panels) vs. wideband (middle panels) late gadolinium enhancement sequences in a patient with Chagas disease. Electroanatomic mapping of the left ventricular endocardial and epicardial surfaces shows good correlation of low voltage areas with areas of delayed enhancement on wideband sequences. Stevens *et al.* Heart Rhythm 2014; 11:289-298.

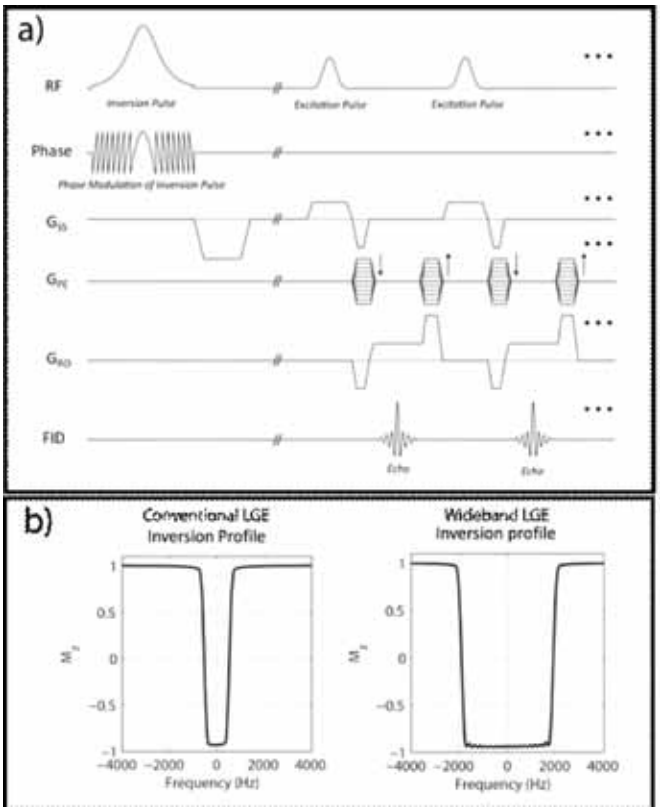

Figure 3 : a) The pulse sequence diagram of the wideband LGE MRI technique. b) A comparison of the inversion pulse bandwidth between conventional LGE and the wideband LGE. The wideband LGE inversion pulse approximately quadruple the inversion pulse spectral bandwidth, which enables elimination of hyper-intensity image artifacts caused by the implanted cardiac devices. From: Do D. *et al.* Heart Rhythm 2018;15: 218.

CONCLUSIONS

The use of MRI in patients with CIEDs has seen major changes over the last decade. While MRI is now widely available with MR conditional CIEDs, it is now being increasingly undertaken with legacy devices following the findings of the MagnaSafe Registry and Nazarian *et al.* studies, both published in 2017 in the New England Journal of Medicine. The most common adverse event appears to be a partial device reset seen in approximately 0.5% of devices following MRI. Changes in battery voltage and lead parameters, while measurable, have been found to be clinically insignificant. The risk of a device problem requiring replacement appears to be <1:1000 for pacemakers and 1:500 for ICDs.

The 2017 HRS Expert Consensus on MRI and Radiation Exposure in Patients with CIEDs shows the marked shift in practice since the 2007 AHA statement [22]. Overall, performing an MRI scan in patients with a non-conditional MR device is given a Class IIA recommendation. The report also underlines the need for a collaborative effort between radiologists and cardiologists, and emphasizes the need for patient monitoring during and after the scan. No guidance is provided for the situation of abandoned or epicardial leads. As always, the benefit /risk ratio needs to be carefully assessed for each clinical situation.

ABBREVIATIONS

AHA: American Heart Association
CIED: Cardiac Implantable Electronic Device
Class IIA Recommendation: Moderate, can be useful/effective/beneficial.
CMR: Cardiac Magnetic Resonance
CRT: Cardiac Resynchronization Therapy
ESC: European Society of Cardiology
HRS: Heart Rhythm Association
ICD: Implantable Cardioverter Defibrillator
LGE: Late Gadolinium Enhancement
MRI: Magnetic Resonance Imaging
RF: Radiofrequency

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