MRI Conditionally Safe Pacemakers
Design and Technology Considerations

Omair Yousuf, MD*, Joseph E. Marine, MD,
Saman Nazarian, MD, PhD

KEYWORDS

• Magnetic resonance imaging • Safety • MRI-conditional • Pacemaker • ICD

KEY POINTS

- MRI scans of conventional (not MRI-conditional) pacemakers and implantable cardioverter-defibrillators (ICDs) can be performed safely under specific conditions in a controlled environment.
- MRI scanning of patients with pacemaker or ICD systems should be undertaken using a multidisciplinary approach that requires personnel trained in device management and advanced cardiac life support, availability of resuscitation equipment and facilities, and a thorough discussion of risk and benefits between patient and physician.
- MRI-conditional pacemaker systems have been redesigned to mitigate electromagnetic interference and heating.
- The safety of MRI in the setting of cardiac implantable electronic devices has been studied mainly using standard scanners with field strength of 1.5-T; therefore, the safety protocols should not be extrapolated to scanners with different field strengths or configurations, such as 3-T and open bore systems.

INTRODUCTION

The use of implantable cardiac electronic devices, including pacemakers, implantable cardioverter defibrillators (ICDs), and/or cardiac resynchronization therapy (CRT) devices, has increased dramatically, due in part to expanded indications for their use, their pivotal role in improving cardiovascular outcomes and mortality, and the aging of society. In parallel, use of MRI as a diagnostic modality has seen significant expansion, with more than 60 million scans performed annually worldwide.[1] This is, in large part, due to the unparalleled soft tissue resolution and lack of ionizing radiation with MRI. It is estimated that up to 75% of patients with implantable cardiac devices will develop an indication for MRI during their lifetime.[2,3] Moreover, the likelihood of needing an MRI doubles after 65 years of age—a demographic that is most likely to receive an implantable cardiac device.[4] Hence, the necessity for MRI is increasingly encountered in this cohort of patients.

Although MRI is a safe technology, implantable cardiac devices are subject to force and torque, heating, current induction, and/or electromagnetic interference in the MRI environment. As a result of reported fatalities, manufacturers of both conventional cardiac devices and MRI equipment consider the presence of an implanted cardiac device an absolute contraindication to MRI scanning. Accordingly, a scientific statement issued by the

Disclosures: None (O. Yousuf, J.E. Marine); Dr S. Nazarian is a scientific advisor to Biosense Webster Inc and Principal investigator for research support to Johns Hopkins University from Biosense Webster Inc. Dr S. Nazarian's research is also supported by grants from the National Institutes of Health (K23HL089333 and R01HL116280).
Johns Hopkins University, Baltimore, MD 21287, USA
* Corresponding author. 1800 N. Orleans Street, Zayed 7125, Baltimore, MD 21287.
E-mail address: OYousuf1@JHMI.edu

Card Electrophysiol Clin 6 (2014) 269–278
http://dx.doi.org/10.1016/j.ccep.2014.02.001
1877-9182/14/$ – see front matter

American Heart Association, American College of Cardiology, and several radiological societies discourage the use of MRI in these patients.[3] They endorse a thorough and careful risk/benefit analysis and recommend performing MRIs only in compelling clinical circumstances.

Patients with an indication for MRI and no other acceptable alternative often must undergo MRI, particularly when the potential benefit of the diagnostic data obtained by MRI significantly outweighs the risk for device failure or other complications. Over the past decade, several studies have concluded that MRI can be performed safely in patients with implantable cardiac devices under specific clinical circumstances in a carefully selected environment with appropriately trained personnel.[5–10] Furthermore, given the increased need for MRI in patients with cardiac devices, there has been strong interest by device manufacturers in the development of pacemakers and lead systems specifically tested for safe but conditional use in the MRI environment.

Box 1
Potential cardiac implantable device complications from MRI

- Inappropriate defibrillator firing
- Asynchronous pacing
- Inhibition of pacing
- Battery depletion
- Induction of malignant tachyarrhythmias
- Power-on-reset
- Reed switch malfunction
- Image artifacts
- Device malfunction and damage
- Force and torque leading to device or lead dislodgement
- Thermal injury leading to myocardial necrosis or perforation
- Death

SAFETY CONCERNS IN THE MRI ENVIRONMENT

The MRI environment has a wide range of potentially deleterious effects on implantable cardiac devices. Risks generally arise from the static and gradient magnetic fields and radiofrequency energy, which in isolation or in concert can cause device malfunction, localized tissue injury, loss of capture, inhibition of pacing, asynchronous pacing, current induction resulting in myocardial capture and arrhythmia, and delivery of inappropriate ICD therapies. The major MRI-induced cardiac device complications are discussed below and also listed in **Box 1**.

Despite the potential for these serious risks, some patients have a strong indication for MRI without an acceptable alternative. If a decision is made for a patient with an implanted cardiac device to undergo MRI scanning, a detailed discussion outlining the risks and benefits along with a documented informed consent should be undertaken between patient and treating physician. Furthermore, the study should be performed with rigorous safety standards, including the presence of personnel trained in device management and advanced cardiac life support, availability of a cardiac electrophysiologist and adequate emergency medical equipment, and appropriate monitoring throughout the study.

Force and Torque

The ferromagnetic components of cardiac devices are subjected to force and torque caused by the intense magnetic field. This situation can theoretically lead to movement of the device generator. The leads have little or no ferromagnetic materials and are unlikely to experience significant force and torque. Device generators implanted after the year 2000 seem to contain less ferromagnetic materials and experience lower force and torque levels. Overall, the risk of device dislodgement, even with acute implants, is exceedingly low. Most studies, however, have restricted MRI during the first 6 weeks after implantation.[11–13] This safety window has been implemented in studies not because of a high risk of MRI-induced dislodgement during the first 6 weeks but because of the high risk of spontaneous (not MRI-induced) dislodgement, which would bias the safety results. At the authors' institution, several MRI examinations have been performed safely with an absolute clinical necessity in the acute postimplant period.

Tissue Heating and Injury

Leads can act as antennas and may amplify local energy deposition at the lead tip or locations near the lead, thus resulting in heating of the surrounding myocardial tissue and edema or necrosis. Clinically, a temperature increase at the lead tip may result in increasing pacing thresholds, loss of capture, or myocardial perforation.[14] Troponin elevations have been reported in 4 of 113 MRI scans performed in a 1.5-T scanner in patients with a variety of cardiac implantable devices.[15] These enzyme elevations may reflect tissue necrosis from thermal injury.