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Position Statement

Canadian Heart Rhythm Society and Canadian Association of Radiologists Consensus Statement on Magnetic Resonance Imaging With Cardiac Implantable Electronic Devices

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ABSTRACT

Magnetic resonance imaging (MRI) has historically been considered contraindicated for individuals with cardiac implantable electronic devices (CIEDs) such as pacemakers and implantable defibrillators. Magnetic resonance scanners produce magnetic fields that can interact negatively with the metallic components of CIEDs. However, as CIED technology has advanced, newer MRI conditional devices have

RÉSUMÉ

L'imagerie par résonance magnétique (IRM) a traditionnellement été contre-indiquée chez les individus porteurs d'un dispositif cardiaque électronique implantable (DCEI) comme les stimulateurs cardiaques et les défibrillateurs implantables. Les appareils d'imagerie par résonance magnétique produisent des champs magnétiques pouvant interagir de façon négative avec les composants métalliques des DCEI. Cependant, à

Traditionally, it has been considered a contraindication to image patients who have cardiac implantable electronic devices (CIEDs) such as pacemakers and implantable defibrillators with magnetic resonance (MR) imaging. MR scanners produce magnetic fields that can interact negatively with the metallic components of CIEDs. Risks can include migration and dislodgement of device components; generation of energy currents that might damage the device and the myocardium; oversensing or undersensing caused by magnetic artifact leading to device malfunction; and rarely, generation of life-threatening arrhythmias.[1] Even though MR scanning of these patients is associated with a low risk of life-threatening adverse events, the possibility of serious sequelae has meant that most CIED patients are denied MR examination.

It is estimated that a patient has a 50%-75% probability of requiring an MR examination over his or her lifetime after CIED implantation.[2] Although alternative imaging modalities

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been developed that are now in clinical use and these systems have had demonstrated safety in the MRI environment. Despite the supportive data of such CIED systems, physicians remain reluctant to perform MRI scanning of conditional devices. This joint statement by the Canadian Heart Rhythm Society and the Canadian Association of Radiologists describes a collaborative process by which CIED specialists and clinics can work with radiology departments and specialists to safely perform MRI in patients with MRI conditional CIED systems. The steps required for patient and scanning preparation and the roles and responsibilities of the CIED and radiology departments are outlined. We also briefly outline the risks and a process by which patients with nonconditional CIEDs might also receive MRI in highly specialized centres. This document supports MRI in patients with MRI conditional CIEDs and offers recommendations on how this can be implemented safely and effectively.

mesure que la technologie des DCEI avançait, de plus récents dispositifs magnétocompatibles ont été conçus et sont maintenant utilisés en clinique. De plus, ces systèmes se sont avérés sécuritaires dans un environnement d'IRM. En dépit des données qui appuient ces systèmes de DCEI, les médecins se montrent réticents à réaliser l'examen d'IRM chez les porteurs de dispositifs magnétocompatibles. Cet énoncé de position commune de la Société canadienne de rythmologie et de l'Association canadienne des radiologistes décrit un processus de collaboration qui permet aux spécialistes et aux cliniques de DCEI de travailler avec les départements et les spécialistes en radiologie pour réaliser l'IRM en toute sécurité chez les patients porteurs de DCEI magnétocompatibles. Nous exposons les grandes lignes des étapes nécessaires à la préparation du patient et de l'examen, ainsi que les rôles et les responsabilités des départements de DCEI et de radiologie. Aussi, nous soulignons brièvement les risques et un processus qui permettrait aux patients porteurs de DCEI non magnétocompatibles de subir l'IRM dans des centres hautement spécialisés. Ce document appuie l'IRM chez les patients porteurs de DCEI magnétocompatibles et présente des recommandations pour une mise en place sécuritaire et efficace.

such as computed tomography (CT) are available, they might not provide imaging detail or diagnostic yield equivalent to MR imaging in selected cases. To date, MR scanning has been safely performed in selected CIED patients at specialized centres with high imaging expertise, but this practice has not been widespread. To overcome this limitation, manufacturers have modified the design and programming of CIEDs to minimize the potential risks associated with MR scanning. As a result, MR-compatible CIED systems (currently labelled as "MR-conditional") are now available for clinical use, with more of such emerging technologies being introduced in the future (Table 1).

Despite the availability of these newer, MR-conditional CIED systems, physicians remain reluctant to perform scanning of MR-conditional systems because of lingering concerns of risk. Furthermore, accurate identification of patients with MR-conditional systems can be challenging. Accordingly, the purpose of this consensus statement document is to outline a process by which cardiac device and imaging specialists can work collaboratively to facilitate MR scanning for patients with MR-conditional CIED systems. The risks, limitations, and details of the technology are summarized. Finally, this document addresses the issue of MR scanning of non−MR-conditional CIED systems—a practice that is currently reserved for highly selected patients in centres with extensive MR imaging expertise. Ongoing studies are being conducted to assess the safety of MR scanning for existing CIED products that were originally designed without intent for exposure in the MR environment. These products are referred to as "legacy" products and will be referred to as such in this document.

Table 1. Definitions of MR-conditional devices

Terminology	Definition
MR-safe	An item that poses no known hazards in all MR environments
MR-conditional	An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. The field conditions that define the specified MR environment include parameters such as: (1) field strength; (2) spatial gradient; and (3) time rate of change of the magnetic field, radiofrequency fields, and specific absorption rate. Additional conditions, such as specific configurations of the item, might be required
MR-unsafe	An item that is known to pose hazards in all MR environments

In 1997, the United States Food and Drug Administration Center for Devices and Radiological Health requested the American Society for Testing and Materials (currently known as ASTM International) to establish a set of standardized definitions to address the safety of medical devices in an MR environment. These definitions are intended for the purpose of labelling claims for medical devices in MR environments. The most recent iteration was proposed in August 2005 (ASTM F2503-05).[3] These definitions are used in this consensus document.[3,4]

MR, magnetic resonance.

Data from Woods et al.[4]

Potential Risks of MR Imaging in Patients With CIEDs

The presence of a CIED system has traditionally been considered a contraindication to performing an MR examination. MR scanners generate a powerful static magnetic field combined with a switching gradient magnetic field and pulsed radiofrequency fields to generate images. Risks associated with MR scanning in patients with CIEDs generally arise from 3 sources: the static magnetic field, gradient magnetic fields, and radiofrequency fields.[5,6] These sources can induce several responses in the CIED including mechanical pull, heating, torque, vibration, and electrical stimulation (Table 2). The static magnetic field can interact with ferromagnetic components on CIEDs to generate unexpected forces that can move and potentially dislodge leads. It can also unpredictably trigger the magnetic sensor in CIEDs that could trigger inappropriate magnet mode pacing in pacemakers or inhibit device therapy for implantable defibrillators. The static field can also cause reed switch closure in some devices (which would also inhibit therapy) or cause distortion in the CIED electrocardiograms

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