

Guidelines for Managing Patients with Coronary Artery Stents With Unknown Labeling Information Referred for MRI Procedures

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In the clinical magnetic resonance imaging (MRI) setting, there is often misunderstanding associated with the management of patients with coronary artery stents, including confusion regarding stents labeled “MRI Safe/MRI Compatible” (i.e., due to labeling applied prior to the change in terminology, 2005) or “MR Conditional”, the timing of performing MRI following stent placement, and regarding what MRI limitations may exist (e.g., those related to the acceptable static magnetic field strength, maximum spatial gradient magnetic field, whole body averaged specific absorption rate or SAR, and other conditions)(1-3). This may result in restricted access to MRI for certain patients, particularly those with coronary artery stents for which there is unknown labeling information.

Notably, the previous belief that it may be necessary to wait six weeks or longer after implantation of certain coronary artery stents to allow for endothelialization or other mechanism to prevent migration has been refuted because there are no known coronary artery stents made from ferromagnetic metallic materials (4-22).

MRI labeling information exists for many coronary artery stents (3, 22). By following the pertinent MRI labeling information (i.e., presented in the Instructions for Use, Patient Identification Card, etc.), patients with coronary artery stents have safely undergone MRI examinations, including those performed at 1.5- and 3-Tesla. Importantly, there has never been an adverse event reported in association with performing MRI in patients with these particular implants.

Unfortunately, the standard policy that MRI labeling information is required before allowing MRI in patients with coronary artery stents limits access to this important diagnostic imaging modality for those patients for which labeling is unavailable. However, in consideration of the relevant peer-reviewed literature and other related documents, it is acceptable and safe to perform MRI

examinations in all patients with coronary artery stents by following specific guidelines developed by taking into consideration possible safety concerns (i.e., magnetic field interactions and MRI-related heating) for these implants.

By adhering to these admittedly conservative MRI conditions, all patients with coronary artery stents can benefit from the diagnostic imaging information provided by one of the most important noninvasive imaging modalities.

Guidelines. The following guidelines apply to using MRI in all patients with coronary artery stents (including two or more overlapped stents) that have unknown labeling information:

(1) Patients with all commercially available coronary artery stents (including drug-eluting and non-drug eluting or bare metal versions) can be scanned at 1.5-Tesla/64-MHz or 3-T/128-MHz, regardless of the value of the spatial gradient magnetic field.

(2) Patients with all commercially available coronary artery stents can undergo MRI immediately after placement of these implants.

(3) The MRI examination must be performed using the following parameters:

- 1.5-Tesla or 3-Tesla, only
- Whole body averaged specific absorption rate (SAR) of 2-W/kg, operating in the Normal Operating Mode for the MR system
- Maximum imaging time, 15 minutes per pulse sequence (multiple sequences per patient are allowed)

Important Note: Any deviation from the above MRI conditions requires prior approval by the Radiologist or supervising physician.

Important Note: These guidelines must be reviewed on an annual basis to confirm that no new coronary artery stent has become available that substantially deviates from the above MRI conditions or that is labeled, MR Unsafe.

Important Note: This information does not apply to other stents such as peripheral vascular stents, abdominal aortic aneurysm (AAA) stent grafts, biliary stents, ureteral stents, or stents used for other applications (e.g., tracheobronchial stents, esophageal stents, etc.).

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