Article published online: 2024-05-03

Magnetic Resonance Imaging Safety Board for India

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Indian J Radiol Imaging

Magnetic resonance imaging (MRI), a widely used imaging technique in healthcare diagnostics, has excellent soft tissue contrast with nonionizing radiation exposure.[1] The three electromagnetic fields in MRI, static magnetic field, time-varying fields, gradient and radio-frequency fields, cause different safety risks.[2–5] Vertigo, nausea, projectile, biomedical implant and device-related events, ferromagnetic translational forces, peripheral nerve stimulation, heat deposition, and acoustic noise are some adverse events related to electromagnetic fields.[2,6–11] The use of MRI scanners with higher capabilities in diagnostic and teaching centers can lead to an increase in magnitude of safety-related incidents.[4] The consequences of adverse events can be reduced by improvements in the reporting and learning from adverse incidents, understanding their causes, and taking prompt action to prevent similar incidents in the future.[4,12–15] MR safety incidents are grossly underreported and more measures are needed to address MR safety issues.[16–19]

Adverse events associated with static magnetic fields include interactions with human tissue, projectiles, and malfunction or movement of implants or monitoring devices.[4] The risks associated with radio-frequency fields include specific absorption rate issues, tissue heating, burns, implant heating, and implant interference effects.[4,20] Peripheral nerve stimulation and acoustic noise, including potential interference with implants or monitoring devices, are the major risks associated with time-varying gradients.[4,20] The American Society of Testing and Materials International Committee has identified three MRI safety categories: MR safe, MR conditional and MR unsafe, and labels each with an associated icon.[21] Acute sensory effects, including a metallic taste, nausea and vertigo, are of particular concern as 7T systems are introduced into clinical practice.[11] Thermal injuries were a major contributor (59%) in the Food and Drug Administration MAUDE MRI adverse event database.[22] Advances in other industries, as in clothing manufactured with invisible silver-embedded microfibers, can also cause newer forms of thermal injuries.[23] The United Kingdom Medicines and Healthcare Products Regulatory Agency recommends the removal of medicinal patches that may contain metal if removal will not compromise patient treatment.[24]

The reporting of critical incidents is important to further improve or refine safety standards and processes. Kihlberg et al reported that only 38% of critical incidents were reported and that several of the unreported incidents could have turned catastrophic.[17] Hansson et al observed that 16% of MR safety incidents had the highest severity or worst-case scenario score, that severe adverse events still exist despite safety protocols, and critical incidents are poorly shared within the team and are preventable.[25]

We recommend the formation of a dedicated MR safety board in India with clear roles, responsibilities, and statutory power. The leadership of the MR safety board must include the state, regional and national level leadership of the respective Indian Radiological and Imaging Association (IRIA) chapters, and include other stakeholders like medical physicists, radiation specialists, and biomedical engineers, in coordination with the health ministry at the local and national level. Leadership by Radiology associations can bring in the necessary expertise on clinical imaging protocol guidelines. The MR safety board must focus on the development of protocols and processes, systems, communication

DOI https://doi.org/10.1055/s-0044-1785682.
ISSN 0971-3026.

Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

channels and training with the demarcation of responsibilities, and develop processes for accreditation including certification and re-certification, audits, and compliance. At the institutional level, the MR safety committee must be led by the Director of Radiology services, with a dedicated MR safety officer and level 1 and 2 MR personnel. Several specific and interlinked actions include the identification and appropriate zone demarcation implementation plans with the help of industry partners, educational programs for professionals that work in MR sites, development of clear MR safety procedures including screening forms and protocols, and rigorous but easily manageable incident-reporting systems with focus on prevention and learning from mistakes.[19] The National Health Mission India guidelines for medical devices for radioimaging departments focus on the clinical purpose and technical characteristics of the device, and environmental and operating conditions and do not explicitly include safety practices and audits as part of the guidelines. The MR safety board, under the leadership of IRIA, can complete this important missing link and help to develop standards for optimal and safe care for patients who undergo an MR imaging procedure in India.

Conflict of Interest
None declared.

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