Safety standards for patients

Active and passive implanted medical devices; How to use technical data sheets for implanted medical devices; exposure to RF fields

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Summary

The greatest risk from the static magnetic field is the force exerted on ferromagnetic objects which accelerates them towards the scanner. Such projectiles have caused fatalities.

Screening of patients for implanted ferromagnetic material is essential.

The radiofrequency magnetic field and its associated electric field deposit energy within the tissues which may lead to tissue heating.
This depends also on the type of pulse sequence and specific pulse sequence parameters used.

Dramatic increases in both magnetic resonance imaging (MRI) usage and cardiac device-based therapy passive implnats have resulted in an estimated 50–75% probability of a patient being indicated for an MRI over the lifetime of their device.
Some recent studies have demonstrated “safe procedures” and “no adverse events” in the limited populations, clinical situations, and specific devices and lead orientations tested.
While these investigations are useful to help ascertain the hazards for patients with active and passive devices, they do not demonstrate clear freedom from risk.
All components of active implantable systems must be engineered during the design stage to provide safety in current and evolving MR environments.
Device manufacturers need to secure regulatory approval to confirm their products' safety under multiple clinical and technical variables.

The instructions for use shall declare that MR scanning is contra-indicated for PATIENTS with implants, the exception being PATIENTS with known MR safe or MR conditional implants that can be scanned according to the conditions specified in the implant labelling. The instructions for use shall describe the following RISKS associated with the scanning of PATIENTS with active or passive implants containing metal or other magnetic and/or electrically conductive materials:
– the electromagnetic fields might exert strong forces on such implants;
– the electromagnetic fields might interfere with the operation of active devices;
– the implants might cause significant artefacts in the MR image;
– MR scanning when an implant is present might cause HARM such as internal heating that results in tissue damage, loss of physiologic function and serious injury.
The instructions for use shall also address the following related to MR scanning of PATIENTS with MR conditional implants:
– the MR scan should only be conducted based on the result of a risk versus benefit assessment by the RESPONSIBLE ORGANIZATION;
– the MR OPERATOR shall adhere to the conditions of use defined in the MR conditional implant labelling as described in the ACCOMPANYING DOCUMENTS of the implant MANUFACTURER;
– the instructions for use shall include a statement to explain the roles and responsibilities of the MR MANUFACTURER, the implant MANUFACTURER and the MR OPERATOR in scanning of PATIENTS with MR conditional implants.

For the different implants, the manufactures must write a specific Guidance for Adjusting MRI Scan Sequence in different tomographic conditionas. In general the physical sequences parameters are SAR, dB/dt and Bl+rms Values; on the other hands specific prescription related to the MRI scanner and coil prescription shuold be indicated into the device guideline.

During the lecture the state of art of the procedures necessary to prevent patients risks will be discussed and some practical examples will be discussed with the students.