MRT - bei Patienten mit Herzschrittmacher oder Defibrillator

(Nur geschlossenes MRT-System mit zylindrischem Magnet und pektoraler Implantation)

Erarbeitet von der Arbeitsgruppe MRT im GUK 812.5 der DKE

Dieses Informationsblatt dient der Vorbereitung einer MR-Untersuchung und ist zeitnahe zu einer solchen Untersuchung zu erstellen.

Der bei Herrn/Frau:.....geb. ..... implantierte Impulsgenerator einschl. der Elektrodensonden (s. Ausweis) ist als bedingt MRT-sicher zertifiziert. Bei einer MR-Untersuchung müssen besondere Parameter und Hinweise beachtet werden. Diese werden nachstehend gelistet.

Parameter	**Absolut-Vorgaben der Hersteller**
Scanbereich (EXZ / FBS)	
Statisches Magnetfeld B_0	[T]
räumlicher Feldgradient ∇B	≤ [T/m]
Zeitliche Änderung des magnetischen Feldes dB/dt pro Achse	≤ [T/m/s]
Gradient der des magnetischen Feldes pro Achse	≤ [mT/m]
spezifische Ganzkörper-Absorptionsrate (SAR)	≤ [W/kg]
Kopf-Absorptionsrate (SAR)	≤ [W/kg]
zusätzl. lokale Sende- und Empfangsspulen (Kopf / Extremitäten)	
Gesamtuntersuchungszeit (außerhalb Brustbereich)	≤ [min]
Gesamtuntersuchungszeit (innerhalb Brustbereich)	≤ [min]
Wartezeit für neue Untersuchung	≤ [min]
Umprogrammierung in den MRT-Modus (autom. / Aktivator / Kardiologe)	
Zeitlimit für den MRT-Modus	[h]
andere metallische Implantate < cm: Entfernung von den Sonden	> [cm]
Implantationszeit > [Wochen]	ja / nein [⊗]
Reizschwelle ≤ [Volt] @ [ms]	ja / nein [⊗]
Impedanz der Stimulationssonden jeweils [Ω] bis [Ω]	ja / nein [⊗]
Impedanz der Schocksonde [Ω] bis [Ω]	ja / nein [⊗]
Batteriestatus weder ERI noch EOS	ja / nein [⊗]
Verlust der Signaltonfunktion (ja / nein/ nicht vorhanden)	
sonstige Anforderung	

= **unterlegte Felder können automatisch vom Programmiergerät generiert werden, anderenfalls müssen diese vom Kardiologen eingetragen werden. Je nach Implantat sind unterschiedliche Parameter zu beachten.**

FBS = Full Body Scan
EXZ = Exclusion Zone (Scan- Ausschlussbereich z.B. C1 - T12)
1 T/m = 200 Gauß/cm
⊗ = Diese Anforderungen müsssen mit „ja" beantwortet sein.

Hinweise:

1. Der Patient muss fieberfrei sein und darf keine Beeinträchtigung der Wärmeregulation haben.
2. Es wurden keine Elektrodenverlängerungen oder Elektrodenadapter verwendet.
3. Es sind keine andere aktive / stillgelegte kardiologische Implantate vorhanden
4. Der Patient befindet sich ausschließlich in Rückenlage / Bauchlage.
5. Während der Untersuchung und im Betriebsmodus „MRT" erfolgt Überwachung von mindestens einem der folgenden Parameter: Blutsauerstoffsättigung, Blutdruck oder EKG.
6. Die EKG-Überwachung muss für ein MRT-Umfeld zugelassen sein.
7. Notfallausrüstung zur Wiederbelebung mit entsprechendem Personal steht zur Verfügung und muss, soweit diese nicht MRT-tauglich ist, außerhalb der Schutzone verbleiben.
8. Im MRT-Modus werden keine gefährlichen Herzrhythmen erkannt und keine Therapieschocks abgegeben.
9. Unmittelbar nach der MRT-Untersuchung muss der Patient kardiologisch nachkontrolliert werden.
10. Vor Erstellung dieses Informationsblattes sind die aktuellen Veröffentlichungen / Vorgaben der Implantathersteller auf eventuell abweichende Empfehlungen zu überprüfen.

Datum: Arzt:

Implantable Infusion Pumps in the Magnetic Resonance (MR) Environment: FDA Safety Communication - Important Safety Precautions

[Posted 01/11/2017]

AUDIENCE: Cardiology, Surgery, Emergency Medicine, Radiology

ISSUE: The FDA has received reports of serious adverse events, including patient injury and death, associated with the use of implantable infusion pumps in the MR environment. These reports describe medication dosing inaccuracies (e.g., over-infusion or under-infusion, unintended bolus) and other mechanical problems with the pump (e.g., motor stall, pump not restarting after a Magnetic Resonance Imaging (MRI) exam).

MRI systems provide images of the internal structures of the body that can be useful in diagnosing a wide variety of diseases and conditions. However, the MR environment presents safety hazards for patients with implantable infusion pumps. Only implantable infusion pumps labeled as MR Conditional may be used safely within an MR environment, and only under the specified conditions of safe use. The specific conditions that health care practitioners and patients should follow before, during, and after the MRI exam vary by the make and model of the implantable infusion pump system. Importantly, each implantable pump model may have unique conditions that must be followed in order for a patient to safely undergo an MRI exam. Failure to adhere to these conditions can result in serious injury or death.

An analysis of adverse event information and manufacturer labeling alerted the FDA to a potential safety problem with the use of implantable infusion pumps in the MR environment. The FDA is working with the applicable manufacturers to update MRI safety information in their labeling to ensure that instructions for the safe use of these devices are clear and up-to-date with current terminology and definitions.

BACKGROUND: Implantable infusion pumps are devices that are surgically implanted under the skin, typically in the abdominal region. They are connected to an implanted catheter and are used to deliver medications and fluids within the body. Implantable infusion pumps are periodically refilled with medications or fluids by a health care provider. Implantable infusion pumps may be used to treat chronic pain, muscle spasticity, and many other diseases or conditions.

Magnetic Resonance Imaging (MRI) is a medical diagnostic exam that creates images of the internal structures of the body by using strong magnetic fields and radio waves (radiofrequency energy). These images provide information to physicians and can be useful in diagnosing a wide variety of diseases and conditions. Some medical devices, including some implantable infusion pumps, can be affected by the strong magnetic fields associated with MRI.

RECOMMENDATIONS: See the FDA Safety Communication for recommendations specific to MRI technologists, radiologists, surgeons, MRI prescribers, and implantable infusion pump managers.

Patients with implantable infusion pumps and their caregivers:

- Be aware that specific instructions must be followed by your health care providers and MR technologist before, during, and after an MRI exam. These instructions may differ by manufacturer and model of the pump.
- If you are scheduled for an MRI, make sure your physicians and the MR technician know that you have an implantable infusion pump.
- Be able to identify the make and model of your implantable infusion pump. Most patients are provided with an "implant card" that lists this information.
- Bring the implant card for your implantable infusion pump with you when you go for your MRI exam. Before you can safely have an MRI exam, your health care team will need to identify your specific pump model to locate the specific MRI safety information for your pump. If there are any questions about the make and model of implantable infusion pump you have, contact the physician who manages your pump and do not have the MRI exam until the specific implantable pump model is identified.
- Consider obtaining a medical alert bracelet or necklace in case of an emergency situation. Include information to notify medical professionals that you have an implantable pump and that MRI precautions need to be followed.
- Be aware that MRI exams may affect the function or programming of your infusion pump, even when the specified conditions of MR Conditional use have been followed. For example, your implantable pump may need to be checked and/or reprogrammed by your physician before and after your MRI.
- Only implantable infusion pumps labeled as MR Conditional may be safely scanned, and only under the specific conditions of safe use. Consult with your physician and the MR technician to determine whether it is safe for you to have an MRI.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[01/11/2017 - Safety Communication - FDA]