Guideline
Use of MRI in patients with implants

General Introduction

This is the English translation of the Dutch guideline
'richtlijn Gebruik MRI bij patiënten met implantaten'
The Dutch version is officially approved by the Netherlands Society of Medical Physics (NVKF).

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Colophon

GUIDELINE USE OF MRI IN PATIENTS WITH IMPLANTS

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General introduction

Motivation for the guideline development

Every year more than 750,000 implants are placed in the Netherlands (van der Graaf, 2016). This number increases over time and more and more different types of implants are employed. Many patients with implants will be referred for a diagnostic MRI examination later on in life, a technique that is increasingly used in clinical routine (RIVM, 2023). Based on current information on MRI contraindications of implants, an implant is either classified as 'MR safe' (MRI can be applied without risk) or 'MR conditional' (where MRI can take place safely under specific conditions), or into the category 'MR unsafe'. The additional risk of complications due to the presence of the implant is negligible for the categories 'MR safe' and 'MR conditional'. However, the classification of implants is performed by the implant manufacturer, who sometimes tests the implant in a limited setting and tends to define conservative conditions. In addition, the above classification assumes that one always knows all details of the implant, which is not always the case in clinical practice.

There is a lack of sufficient information in the clinic to properly determine whether the importance of an MRI examination for the patient with an implant that is not guaranteed to be MR safe or conditional outweighs the risk for that patient with respect to the loss of diagnostic information resulting from denying the MRI examination, and , and in some cases weighing the risk in an individual patient against the effect of control measures in a large group of patients. This guideline provides advice on how to deal with this trade-off for specific types of implants and, in some cases, to deviate from the conditions set for MRI by implant manufacturers.

Purpose of the guideline

The aim is to improve and guarantee the quality of the MR safety expert's advice to the medical professional, thus ensuring safety and access to MRI examinations for patients with implants. This guideline is focused on implants for which it is not entirely clear whether or not an MRI exam is safe, with the aim of making a risk assessment. In addition, the guideline is aimed to save time in practice as modules for certain implants provide recommendations for generic policies, eliminating the need to obtain further information about the specific implant model for each individual case.

With this guideline, therefore, a better estimation of the health risk of an MRI examination in a patient with an implant can be made and compared to the potential health benefit of the MRI exam for that patient, or to the health benefits of a larger group of patients when weighing up screening measures. Currently different hospitals have varying policies in case of implant information lacking with respect to whether the patient can be scanned, and if this is the case, with respect to which (conservative) scan conditions should be applied. This guideline can therefore result in improved availability of MRI for certain patients and in certain hospitals, and in other cases or hospitals it could result in a better substantiated advice of possible limitations for the MRI exam.

Demarcation of the guideline

This guideline assumes that the hospital in which it is applied has a well-functioning MRI safety policy in place, based on good practices adopted worldwide to create a safe environment around MRI systems (ACR Manual 2020; Cross, 2018; Sammet, 2016, NVKF 2019). Within the framework of such a policy, for example, each patient is screened for possible contraindications for undergoing the MRI scan prior to that examination.

This guideline is intended to be used when patients are referred for an examination on a whole body MRI scanner with horizontal closed bore superconducting magnet with a field strength of 1.5 or 3 Tesla (T) and have an implant, according to the individual screening of the patient prior to the MRI examination. The systems chosen to cover more than 95% of all diagnostic MRI systems in the Netherlands. Other types of MRI systems are not considered.

The guideline contains five modules:
Module MRI with a cerebral aneurysm clip (authorized 2019, update planned 2025)

- Some old types of cerebral aneurysm clips are an absolute contraindication for MRI, and can be fatal to the patient. Importantly, it is not always possible to determine exactly what type of clip was implanted in a patient, and therefore whether there is a risk. This module focuses specifically on the question of how to properly assess this risk in that case. The module describes the MRI safety policy for patients with a cerebral aneurysm clip.

Module MRI with a prosthetic heart valve, annuloplasty ring or transcatheter mitral valve replacement (authorized 2019)

- Many different types of prosthetic heart valves and annuloplasty rings exist, with a large number of those implants being 'MR conditional' with different conditions per type. The manufacturer of the implant has the freedom to specify the conditions, resulting in a wide variety of conditions. In addition, these conditions are often quite conservative, as a result of which some risks are overestimated. There are obvious differences in policy on how to scan patients with prosthetic valves between hospitals in the Netherlands. The aim of this guideline is to define a clear and unambiguous guideline for MRI scans of patients with a prosthetic heart valve, annuloplasty ring or transcatheter mitral valve replacement.

Module MRI with a vascular stent (authorized 2024)

- Vascular stents and vascular grafts are implants that are often used after stenosis repair to keep a blood vessel patent. There is a large variation in types and models of stents. In most cases, the stent manufacturer sets conditions per model under which a patient may undergo an MRI examination. These conditions vary and are often conservative. Screening in which the specific MR conditions of the manufacturer must be determined per patient per MRI examination leads to a lot of work and increases the threshold for MRI. In addition, it regularly proves impossible to determine which type of stent or graft has been implanted.
  The question is whether the actual risks justify an intensive screening policy. There also appears to be a large variation between hospitals in the policy that is implemented. Therefore, a clear policy for hospitals on MRI examination of patients with a vascular stent is desirable.

Module MRI with a hearing implant (authorized 2024)

- For patients with hearing implants, it is often known which implant has been placed in the patient. In this guideline module, both active and passive hearing implants are considered. For active implants, in particular cochlear implants (CI), the starting point is that the brand and type of implant are known, and the manufacturer has published a policy for MR compatibility. For these implants, it applies that, despite the fact that they are often MR conditional, problems regularly occur during or after the MRI examination. This guideline module looks at the risk for the patient of an MRI examination, and gives advice on how to scan in the safest possible way.

In this guideline, the following active implants are considered: cochlear implants, bone conduction implants, auditory brainstem implants (ABI), and active middle ear implants. Only auditory ossicle prostheses are considered under passive implants.
This module has not been translated to English.

Module MRI with a cardiac implantable electronic device (CIED) (authorized 2024)

- More and more patients have a pacemaker or implantable cardioverter defibrillator (ICD). Many new systems are MR conditional, and can therefore be scanned under certain conditions. However, there is also a large group of patients who have a pacemaker/ICD that is not MR conditional. Recently (2021), new pacemaker guidelines have been published by the European Society of Cardiology (ESC), which also provide recommendations for MRI examination. On the one hand, this is a translation of existing international guidelines to the Dutch situation. On the other hand, there is a need for advice in policy on how to deal with electronic cardiac implants that have not been classified MR conditional by the manufacturer. Finally, there is an increasing group of patients who have abandoned leads, and the question is what the best policy is for these patients.
  In addition to pacemakers and ICDs, insertable loop recorders or cardiac monitors are the third group of electronic cardiac implants. MR conditions for these implants are simpler, and are included in this module for the sake of completeness.
  This module has not been translated to English.

Intended users of the guideline

The guideline is written for use by MR safety experts such as medical physics experts. In addition, the guideline may be informative to all professionals involved in planning MRI in patients with implants, i.e., radiologists, MR technologists and physicians referring for MRI.

Structure of the considerations in the modules

In addition to scientific literature, the information provided by manufacturers on the MR safety of their implants is of importance. This information is described in the MR safety databases of implants: partly in the freely accessible database of Prof. Frank Shellock www.MRIsafety.com, and partly in the commercial database of MagResource (MR:comp GmbH, Gelsenkirchen, Germany). A relevant summary for each module is included at the beginning of the considerations.

In addition, information from databases containing incident reports is important for this guideline. For each module relevant databases have been searched.

Finally, the considerations of each module have a fixed structure because the risks, when scanning patients with implants in the MRI scanner, can in general be classified into the following main classes:

1. Risk of displacement and rotation of the implant due to the presence of the static magnetic field and the spatial gradient of this field
2. Risk of implant heating due to interaction with the RF field
3. Risk of vibration or induction of currents by the oscillating magnetic field gradients applied for the spatial encoding of the MRI signal
4. Presence of artifacts in the MR image
5. Risk of forces due to the Lenz effect during rapid movement of conductive implants in the static magnetic field of the MRI scanner
6. Risk of interference with implant function

Definitions and terms

For implants the general international terminology of (ASTM, 2013) is followed:

- MR safe: an item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic.
- MR conditional: an item with proven safety in the MR environment within defined conditions. At a minimum, the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields should be addressed. Additional conditions, including specific configurations of the item, may be required.
- MR unsafe: an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

However, not all implants can be classified into these categories. For example, an implant that does contain metal and has not been proven to be safe, but that is known not to pose any unacceptable risk to the patient.

The 2013 ASTM definition was used while drafting this guideline. Notably older literature is based on an older definition for which reason one can encounter devices being declared 'MR safe' in that literature whereas - according to the newer ASTM definitions - they are now labeled 'MR conditional' (e.g. limited to 1.5 T). In the literature summaries in this guideline the above mentioned 2013 ASTM definition is used and the text from older publications has therefore been rephrased whenever appropriate.

MR allowed for 1.5 and 3 T

This guideline uses the additional term 'MR allowed for 1.5 and 3 T'. This is a form of MR conditional where the use of MRI in patients with these implants is allowed when using a whole body MRI system with a horizontal closed bore superconducting magnet with a field strength of 1.5 T or 3 T without further conditions.

MR safety expert

The MR safety expert (MRSE) is specified by the EFOMP (Hand, 2013) and recently ratified by a wider range of scientific associations including the ISMRM, ESR and ESMRMB (Calamante, 2016). In Dutch practice these are often medical physics experts with subspecialty Radiology and Nuclear Medicine and with sufficient knowledge of MRI, or physicists specialized in MRI.

MR safety officer

The MR safety officer (MRSO) as specified by the EFOMP (Hand, 2013) and recently ratified by a wider range of scientific associations including the ISMRM, ESR and ESMRMB (Calamante, 2016). In Dutch practice, for human MRI systems this is often a specialized MR technologist.

Classification of risk estimation

The severity of a risk is typically quantified by the probability of its occurrence on the one hand and the severity of the harm on the other hand.

For the severity of the injury, the classification is based on NEN-EN-ISO 14971 (NEN, 2012). This standard describes risk management for medical devices. However, the classification has been simplified into 2 categories with the definition of calamity as given in the NEN 8009 standard on safety management systems for hospitals (NEN, 2018), see table 1.

Table 1: qualitative description of severity of implant risk

Generic term	Description
Calamity	Fatal or permanent effects (other than scars)

Moderate	Restorable or minor injury or loss of function

For the probability that a complication will occur in an individual MRI examination, the following classification from the NEN-EN-ISO 14971 standard (NEN, 2012) has been used, see table 2. This has been further specified with a quantitative translation into the probability of occurrence, because clinical risks when withholding an MRI examination are sometimes (only) known in qualitative measures. This makes it possible to make a better assessment by comparing both probabilities.

Table 2: qualitative description and quantitative translation of probability

Qualitative description	Quantitative translation into chance
To be expected	0.1 to 1
Unusual	0.01 to 0.1
Rare	0.001 to 0.01
Unlikely	< 0.001

If multiple risks of complications are identified, it has added value to present the risks in a matrix, see table 3.

Table 3: example of a risk matrix in which two risks are presented

		Severity	
		Moderate	Calamity
Probability	To be expected	*R1*	
	Unusual		
	Rare		*R2*
	Unlikely		

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Accountability

Authorization date and validity
Last assessed: April 2024

Guide to the reader
Only the Dutch version of this Guideline was used for authorization. The guideline was subsequently translated into English in order for the international community to take note of the content of the Guideline.

Working method
AGREE

This guideline has been developed according to the requirements of the report Guidelines for Medical Specialists 2.0 by the advisory committee of the Quality Council. This report is based on the AGREE II instrument (Appraisal of Guidelines for Research & Evaluation II; Brouwers, 2010; www.agreetrust.org), a broadly accepted instrument in the international community, and on the national quality standards for guidelines: "Guideline for guidelines"(www.zorginstituutnederland.nl). For a step-by-step description of how an evidence-based module is created, we refer to the step-by-step plan Development of Medical Specialist Guidelines of the Knowledge Institute of the Federation Medical Specialists.

Identification of subject matter

Within the NVKF an analysis with a limited scope has led to the choice to develop these two modules.

Clinical questions and outcomes

The clinical questions were formulated by the chairman, working group members and the advisor. Subsequently, the working group inventoried which outcome measures are relevant for the patient, looking at both beneficial and harmful effects. The working group valued these outcomes according to their relative importance in the decision-making around recommendations, as critical (critical for decision-making), important (but not critical) and unimportant. The working group also defined, at least for the critical outcome measures, which differences they considered clinically relevant (to the patient).

Strategy for search and selection of literature

For the separate clinical questions, specific search criteria were formulated and published scientific articles were searched in (several) electronic databases. Furthermore, studies were scrutinized by cross-referencing for other included studies. The studies with potentially the highest quality of research were looked for first. The working group members selected literature in pairs (independently of each other) based on title and abstract. A second separation was performed based on full text. The databases, search terms and selection criteria are described in the modules containing the clinical questions. The search strategy can be retrieved from the Guidance database, see the tab 'Search accountability' for further details.

Quality assessment of individual studies

Individual studies were systematically assessed, based on methodological quality criteria that were determined prior to the search, so that risk of bias could be estimated. This is described in the "risk of bias" (RoB) tables. The RoB instruments used are validated instruments recommended by the Cochrane Collaboration:

- AMSTAR - for systematic reviews.

- Cochrane - for randomized controlled studies.

Summarizing of literature

The relevant research findings of all selected articles are shown in evidence tables. The most important findings from literature are described in summaries.

Grading quality of evidence and strength of recommendations

The strength of the conclusions of the scientific publications was determined using the GRADE-method: Grading Recommendations Assessment, Development and Evaluation (see http://www.gradeworkinggroup.org/) (Atkins, 2004).

GRADE defines four levels for the quality of scientific evidence: high, moderate, low or very low. These levels provide information about the certainty of the conclusions drawn in a study. (http://www.guidelinedevelopment.org/handbook/) (Schünemann, 2013).

GRADE	Definition
High	• We are very confident that the true effect lies close to that of the estimate of the effect. • It is highly unlikely that the conclusion changes when results of new large scale research is added to the literature analysis.
Moderate	• We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. • It is possible that the conclusion changes when results of new large scale research is added to the literature analysis.
Low	• Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect. • There is a reasonable chance that the conclusion changes when results of new large scale research is added to the literature analysis.
Very low	• We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect. • The literature conclusions are unsure.

In the grading the quality of evidence of the scientific literature in the guideline according to the GRADE-method the borders of clinical decisions play an important role (Hultcrantz, 2017). Crossing these borders would lead to a change in the recommendations. To assess these borders of clinical decisions all relevant outcome measures and considerations should be taken into account. Therefore, these borders are not one to one comparable to the Minimal Clinically Important Difference (MCID). Especially, in situations in which an intervention has no important disadvantages and costs are relatively low, the border of clinical decisions in relation to the efficacy of the intervention will be at a lower value (closer to the zero-effect) than the MCID (Hultcrantz, 2017).

Drawing conclusions

For each relevant outcome measure, the scientific evidence was summarized in one or more conclusions based on literature where the level of evidence was determined according to the GRADE methodology. The working group weighed the beneficial and harmful effects of the intervention (overall conclusion). The overall evidential value was determined by the lowest evidential value found at one of the critical outcome measures. In complex decision-making processes in which many considerations also play a role in addition to the conclusions from the systematic literature analysis, an overall conclusion was omitted. In that case, the positive and negative effects of the interventions, together with all considerations, were weighed under the heading Considerations.

Considerations (from evidence to recommendation)

In order to propose a recommendation, in addition to (the quality of) the scientific evidence, other aspects were important as well and were taken into account, such as the expertise of the working group members, patient preferences, costs, availability of facilities and organization of healthcare. These aspects were discussed in the paragraph Considerations.

Formulating recommendations

The recommendations answer the clinical question and are based on the available scientific evidence and the most important considerations, and a weighing of the beneficial and harmful effects of the relevant interventions. The strength of the scientific evidence and the weight given to the considerations by the working group together determine the strength of the recommendation. In accordance with the GRADE methodology, a low probative value of conclusions in systematic literature analysis does not exclude a strong recommendation a priori, and weak recommendations are also possible with a high probative value. The strength of the recommendation is always determined by weighing all relevant arguments together.

Knowledge gaps

During the development of the guideline, a systematic literature search was performed. The results of which helped to answer the clinical questions. For each clinical question the working group determined if additional scientific research on this subject was desirable. An overview of recommendations for further research is available in the annex Knowledge Gaps.

Comment- and authorization phase

A draft version of the guideline has been commented on by the involved (scientific) associations, agencies and (patient) organizations. The comments were collected and discussed with the working group. The feedback was used to improve the guideline. Afterwards the working group made the guideline definitive. The final version of the guideline was shared with the involved scientific societies and was authorized by them. The full table with all commentaries (*in Dutch*) can be requested from the Knowledge Institute via secretariaat@kennisinstituut.nl.

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