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Review paper

MRI in patients with a cerebral aneurysm clip; review of the literature and incident databases and recommendations for the Netherlands

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ABSTRACT

Background: In the past ferromagnetic cerebral aneurysm clips that are contraindicated for Magnetic Resonance Imaging (MRI) have been implanted. However, the specific clip model is often unknown for older clips, which poses a problem for individual patient management in clinical care.

Methods: Literature and incident databases were searched, and a survey was performed in the Netherlands that identified time periods at which ferromagnetic and non-ferromagnetic clip models were implanted. Considering this information in combination with a national expert opinion, we describe an approach for risk assessment prior to MRI examinations in patients with aneurysm clips. The manuscript is limited to MRI at 1.5 T or 3 T whole body MRI systems with a horizontal closed bore superconducting magnet, covering the majority of clinical Magnetic Resonance (MR) systems.

Results: From the literature a list of ferromagnetic clip models was obtained. The risk of movement or rotation of the clip due to the main magnetic field in case of a ferromagnetic clip is the main concern. In the incident databases records of four serious incidents due to aneurysm clips in MRI were found. The survey in the Netherlands showed that from 2000 onwards, no ferromagnetic clips were implanted in Dutch hospitals.

Discussion: Recommendations are provided to help the MR safety expert assessing the risks when a patient with a cerebral aneurysm clip is referred for MRI, both for known and unknown clip models. This work was part of the development of a guideline by the Dutch Association of Medical Specialists.

1. Introduction

Although in the Netherlands nowadays only Magnetic Resonance (MR) conditional or MR safe cerebral aneurysm clips are utilized, ferromagnetic aneurysm clips have been used until late in the last century. This treatment is given to patients in various age groups, including young adults. Therefore, patients implanted with an aneurysm clip that is potentially ferromagnetic may present themselves for Magnetic

Resonance Imaging (MRI) examinations for decades to come.

If the model of a cerebral aneurysm clip is known, it is possible to determine whether the patient can safely undergo an MRI examination. However, if the aneurysm clip model is unknown or uncertain, caution is warranted because patients might have received aneurysm clips that pose an absolute contraindication for MRI. For Dutch patients, it is often unknown which model of aneurysm clip was implanted, similar to the situation reported in the USA [1,2]. These patients most often are

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referred for MRI at 1.5 T or 3 T whole body MRI systems with a horizontal closed bore superconducting magnet, as these types of systems cover more than 95% of all diagnostic MRI systems in the Netherlands, and also the majority of MRI systems worldwide. Therefore, we limited this article to MRI on these types of MR systems. Other models of MRI systems are not considered as affected patients on a national basis can be allocated easily to relevant MRI systems.

The primary aim of this article is to review the literature and incident databases on the risks of MRI in a patient with a cerebral aneurysm clip. A secondary aim is to present an overview of the use of ferromagnetic and non-ferromagnetic clips in the Netherlands. Finally, we provide recommendations for a risk assessment prior to MRI examinations in patients with cerebral aneurysm clips, for either known or unknown models. This work has been part of the development of a guideline by the Dutch Association of Medical Specialists (called FMS) for MR safety experts [3–5].

2. Material and methods

2.1. Selection of reviewed articles

A literature search was performed to answer the question "what is the chance of a negative outcome for a patient undergoing an MRI examination while having a ferromagnetic aneurysm clip?". We looked at three aspects: ferromagnetic aneurysm clip models, chance of a negative outcome for an MRI in a patient with a ferromagnetic aneurysm clip and the period of implantation of contraindicated aneurysm clips in the Netherlands.

A search was performed on November 22, 2016 in Pubmed with the following keywords: [[magnetic resonance OR MRI] AND [aneurysm] AND [clip OR clips] AND [publication date > 1970/01/01]] and a second search in ScienceDirect with the keywords: [[magnetic resonance OR MRI] AND [aneurysm] AND [safety] AND [clip OR clips] AND [publication date > 1999/01/01] AND NOT [surgery]]. A preliminary selection was made based on the title and abstract only, rejecting articles not related to the topic of this review. Only articles with an abstract in English were included. This resulted in 63 manuscripts. A second refined selection was then performed based on reading the body of the article by two authors, resulting in 19 included articles. After studying references of these articles, two additional articles were included. Thus, finally 21 papers were selected and included in this manuscript.

Most papers concerned experimental studies, describing magnetic properties and in vitro tests [6–15] or heating effects of the clips [15–17]. Two case studies described MRI scans in patients with ferro-magnetic aneurysm clips, one study on implants that are an absolute contraindication for MRI, and a retrospective patient study in which MRI artefacts due to the presence of aneurysm clips were studied [18,19]. Finally, four letters were found with a warning for 20 ferromagnetic aneurysm clips [1,20–22].

2.2. Selection of reviewed databases

Second, MR related implant databases were searched for aneurysm clips; specifically MRISafety.com and MagResource [23]. In addition, incident databases were searched for incidents related to aneurysm clips and MRI; specifically the medical device recalls database from the FDA (Medical Device Recalls) [24], the Health Inspection Service in the Netherlands (Manufacturer Medical Device Warnings) [25] and the database of the International Consortium of Investigative Journalists ("Implant" and "Event" database) [26]. The search strategy can be found in the full guideline [3]. The guideline, on which this manuscript is based, was approved in 2019 by the FMS for the use in the Netherlands. For the purpose of this manuscript, the FDA MDR (1984–1997), Medsun Reports (2006–2021), and MAUDE (1992 – 2021) databases were searched as well, on October 22, 2021 [27–29].

2.3. Survey

To further investigate the period of implantation of contraindicated aneurysm clips in the Netherlands, a survey was conducted among all heads of neurosurgical departments in Dutch hospitals. We asked from which year on all implanted aneurysm clips in each hospital were nonferromagnetic. Furthermore, we asked what model clips were implanted in the years before. Finally, we asked for the number of clip implantations per year. This survey was completed in the spring of 2018, with a response rate of 100% (eleven departments), in which heads of neurosurgical departments involved locally senior neurosurgeons with a long history at the institute.

In the years before the use of non-ferromagnetic aneurysm clips became a standard of care in a clinic, a significant proportion of the clips used already was non-ferromagnetic. However, we could not unequivocally determine the percentage of these, therefore we assumed all clips were ferromagnetic in order to make an estimate of the certainty that a clip is not ferromagnetic when implanted in the Netherlands. For the estimate at national level, we took into account the number of implantations per institute per year.

For the probability of damage in an individual MRI examination from an unknown aneurysm clip, words of estimative probability are used which could be translated into a quantitative probability: 'to be expected' 0.1 to 1; 'unusual' 0.01 to 0.1; 'rare' 0.001 to 0.01; 'unlikely' < 0.001.

Based on the information obtained from the literature search, the incident database searches and the survey, we present an approach for risk assessment prior to MRI examinations in patients with a cerebral aneurysm clip. In addition to scientific evidence, other aspects such as the expertise of the authors and organization of healthcare were taken into account; this is common practice for guideline development in the Netherlands.

3. Results

3.1. Literature review on the chance of a negative outcome of MRI in a patient with a ferromagnetic aneurysm clip

In the database of MRIsafety.com 349 models of aneurysm clips were listed on June 2018, where a model may have a series of submodels with different lengths. Of these, 173 were classified as 'MR safe', 157 as 'MR conditional' and 18 as 'MR unsafe'. The MR unsafe aneurysm clips were subject to further investigation using information from clip manufacturers using the MagResource database. An overview of MR unsafe aneurysm clips is made, compiled from literature and MR related implant databases (Table 1).

Table 1

List of MR unsafe aneurysm clip models based on risk of ferromagnetic forces.

Codman Vari-Angle (17-7PH)	Kapp, Curved (404 SS), aneurysm clip
Codman Vari-Angle Micro (17-7PH)	Kapp, Straight (404 SS), aneurysm clip
Codman Vari-Angle Spring Micro (17-7PH)	Mayfield (301 SS), aneurysm clip
Drake (301 SS), aneurysm clip	Mayfield (304 SS), aneurysm clip
Drake (DR 14, DR 16, DR 21), aneurysm clip	McFadden (301 SS), aneurysm clip
Downs Multi-Positional, aneurysm clip	Scoville EN-57-J, EN-58-J*
Housepian, aneurysm clip	Sundt-Kees Multi-Angle (17-7PH)
Heifetz (17-7PH)	Pivot (17-7PH)
Cap (405 SS), aneurysm clip	Yasargil aneurysm clip (all FD models)

List compiled from MRI.safety.com, MagResource and the scientific literature.

^{*} The material of the Scoville-Lewis aneurysm clip was replaced from austenite to martensite during the production period [44]. Because of this there is confusion about the MR safety of this aneurysm clip since austenite is assessed as MR safe (Shellock on MRISafety.com, where EN58-J is listed as MR safe at 1.5 T) and martensite as MR unsafe [19,45] as 'EN57 J stainless steel'. However, Burtscher et al. refers to En58J as ferromagnetic [46]. Since it is unclear in the literature this clip should be considered MR unsafe. On the question "what is the chance of a negative outcome for a patient undergoing an MRI examination while having a ferromagnetic aneurysm clip?", it was found in literature that, though it is not impossible for a patient with a ferromagnetic aneurysm clip to undergo the MRI examination without complications, there is also a realistic risk that the examination turns out to be fatal. Estimating the individual risk to the patient, however, is complicated and depends for example on the condition of the vessel wall on which the aneurysm clip is implanted [12,18–21]. Non-ferromagnetic aneurysm clips appear to be safe in the MRI environment [15–17,30].

On the question regarding the period of implantation of contraindicated aneurysm clips, we found no literature data for the Netherlands. Studies mainly from the United States estimated the chance that a cerebral aneurysm clip is ferromagnetic is high for implantation before the mid-80 s and low after the mid-90 s. It should be noted that the implantation of ferromagnetic aneurysm clips continued for some time after the production of these clips ended [13,20,31].

3.2. Known incidents

In total, records of ten incidents mentioning both MRI and cerebral aneurysm clips were found [28,29]. Two incidents were fatal probably due to the MR incompatibility of the aneurysm clip; the first in 1992 was identified both in the literature [18] as well as in multiple reports in the MDR and MAUDE databases (to our interpretation on the same incident) (MDR keys M349790, M359096, M359096, and MAUDE key 1109); a second incident was reported in the MAUDE database in 2001 (328633). Two incidents at the MRI with serious effects probably due to the aneurysm clip were found, one reported in 1993 in the MDR database (M518365), and another in 1997 in the MAUDE database (47858). Two other incidents, in which a patient with a cerebral aneurysm clip died following MRI, were identified in the MAUDE database (with four reports in 2016 and 2018), but in both incidents the aneurysm clip appeared not to be the most plausible cause (5980600 and 55750140 and 5895839, 7289224). The 2016 incident was also reported in the ISMRM safety group, but at that time it was thought to be clip-related. Finally, four reports were found in which MRI was performed without adverse events in a patient with an unknown or expected ferromagnetic cerebral aneurysm clip; one in 1988 in the literature [19], and three cases in the MAUDE database in 2009, 2018 and 2021 (1453661, 7609598, 255079248). The more recent queries in the FDA MDR, Medsun Reports and MAUDE databases did not provide new insights that necessitated any adaptation of the guideline.

3.3. Survey on implanted aneurysm clip models in the Netherlands

The results of the survey were used to determine the time period of implantation of contraindicated aneurysm clips in the Netherlands (Table 2). From this survey we estimated the risk of an aneurysm clip implanted in the Netherlands to be ferromagnetic based on the year of implantation (Table 3).

3.4. Approach for risk assessment

Our risk assessment for the cerebral aneurysm clips is based on the six standard risks for metallic implants in MRI:

 <u>Risk of displacement and rotation of the implant due to the presence</u> of the static magnetic field and the spatial gradient of this field. The effect of displacement and rotation of the aneurysm clip in the magnetic field and the spatial gradient is created respectively by the force that each magnetic material (diamagnetic, paramagnetic and ferromagnetic) experiences in a magnetic field gradient, and by the torque in a magnetic field. For ferromagnetic materials in MRI scanners of 1.5 and 3 T, these forces and torques are large relative to gravity. These materials get magnetically saturated in the bore of an

Table 2

Year of implantation from which it is unlikely that an aneurysm clip would be ferromagnetic, differentiated between hospital of implantation in the Netherlands.

Hospital of Implantation	Year of implantation from which it is unlikely an aneurysm clip is ferromagnetic*
Amsterdam University Medical Center, both locations	1995
Erasmus Medical Center	1989
Elisabeth-Tweesteden Ziekenhuis	1990
Haaglanden Medical Center	1995
Isala	1990
Leiden University Medical Center	1980
Maastricht University Medical Center	2000
Radboud University Medical Center incl. Canisius Hospital	1988
University Medical Center Groningen	1990
University Medical Center Utrecht	1986

 * Based on a survey among all Dutch hospitals where cerebral an eurysm clips have been implanted prior to 2018 (response rate 100%).

Table 3

Expectation that an aneurysm clip is or is not ferromagnetic when the hospital of implantation is unknown in the Netherlands.

Date of placement in the Netherlands	Certainty that aneurysm clip is not ferromagnetic*	Chance that aneurysm clip is ferromagnetic
2000 and later	>99.9%	<0.1%
1995–1999	97%	unknown**
1990-1994	92%	unknown**
1986-1989	47%	unknown**
1980-1985	3%	unknown**
before 1980	0%	>90%

Determined on the basis of survey results in Table 2 and estimated number of implantations per institute.

^{*} When asked in the survey, each institute responded unequivocally to the question as to the date from which all implanted aneurysm clips were non-ferromagnetic. To create this table, it was assumed that in the years before it became unlikely that any ferromagnetic aneurysm clip was implanted in a hospital (Table 2), only ferromagnetic aneurysm clips had been implanted, whereas in these years some of the clips used were already non-ferromagnetic. Therefore, the percentage of non-ferromagnetic aneurysm clips can be higher.

^{**} The use of ferromagnetic aneurysm clips in the 1980 s to 2000 s could not be determined unequivocally.

1.5 or 3 T scanner, in which the displacement force (F_z) is determined by the spatial gradient of the static field (dB/dz), and the maximum torque (T_{max}) determined by the square of the saturated magnetic field [32]:

$$F_z \approx \frac{1}{\mu_0} V B_{sat} \frac{dB}{dz}$$
$$T_{max} = \frac{1}{2\mu_0} V B_{sat}^2 (d - dz)$$

l)

in which μ_0 is the permeability in free space, V the object's volume, and B_{sat} the 'saturation field' at which the magnetization of the implant is saturated. The maximum torque is shaped dependent, and the formula is given for a cylinder with *d* the diameter and *l* the length. The actual torque depends on the angle (θ) between static field (B_0) and length of the cylinder, and is at its maximum at 45°. The dB/dz, of importance for the displacement force, is large at the bore opening, with maximum values near the cover for an 1.5 or 3 T superconducting horizontal bore scanner. Torque is maximized when saturation is reached, typically in the bore. Displacement forces are equal to or less than maximum twisting forces (depending on the shape) [32]. For an unsaturated ferromagnetic cylinder, the displacement force and torque are given by [32]:

$$F_z \approx (2.26\frac{l}{d} + 1)\frac{1}{\mu_0}VB_0\frac{dB}{dz}$$
$$T = \frac{1}{2\mu_0}VB_0^2\frac{d-l}{dl}\sin 2(\theta)$$

The forces for diamagnetic and paramagnetic materials with low magnetic susceptibility, on the other hand, are negligible in these MRI systems [22]. For paramagnetic materials with a high magnetic susceptibility, these forces can be relevant. Each material and object must be considered separately, since forces depend on the magnetic field gradient, the magnetic susceptibility as well as on the shape of the object.

Aneurysm clips are made of various metals and alloys [33]. In the past, many aneurysm clips were made of ferromagnetic material. Early aneurysm clips were made of ferromagnetic stainless steel (such as SS 301-405, or DR). Later on, materials to produce clips were changed to non-ferromagnetic materials using for example alloys that contain titanium, cobalt, chromium or nickel. Examples of such alloys are MP35N, Phynox, and Elgiloy.

The worst possible consequence of displacement and rotation of a ferromagnetic aneurysm clip is vessel damage resulting in a fatal haemorrhage [18]. Two patient deaths were reported in 1992 and 2001, and two cases of serious adverse effects, likely related to displacement [18,29]. But there is also a report of a patient with a ferromagnetic aneurysm clip in a low-field MRI (<0.6 T) in which there were no consequences for the patient [19], and also the MAUDE database mentions three cases of unknown or expected ferromagnetic cerebral aneurysm clip without adverse events. The exact risk is difficult to estimate, and depends on multiple factors. For this reason, ferromagnetic aneurysm clips remain an absolute contraindication for undergoing an MRI study [18,20,34]. Aneurysm clips made of non-ferromagnetic material (such as Phynox, Elgiloy, MP35N, titanium, titanium-based alloys and austenitic stainless steel species) are MR conditional. In May 1994, the FDA requested all aneurysm clip manufacturers data and information regarding the tests performed and, if no tests had been performed, to state in the user information that the device was not tested for compatibility with MR imaging devices [31].

Because of the risk and the obligation of MR safety labeling, all manufacturers for products to the European and North American market have, as far we know, abandoned ferromagnetic materials. As a result, only aneurysm clips implanted some time ago can possibly be made of ferromagnetic material (Table 1). In 1998, a study by Shellock revealed that ferromagnetic aneurysm clips were no longer supplied by the manufacturers [13,22,30]. It is highly unlikely that manufacturers will bring new aneurysm clips that are ferromagnetic onto the market, as MRI diagnostics play a valuable role for neurosurgeons for follow-up in this patient group.

Before 1994, there was no consensus on how to quantify ferromagnetic properties of implants [31]. Studies describing ferromagnetic properties of implants published before that date should therefore be interpreted with caution. In 1994, the American Society for Testing and Materials (ASTM) published a standard requiring that the socalled deflection angle should be measured to evaluate the magnetic properties of aneurysm clips [35]. When this angle is less than 45°, gravity exerts a greater force on the clip than the magnetic field of the MRI scanner. At that time the ASTM thus only recommended a test for displacement, but not a test for torque. A test for torque was added in 2011 [36]. In case of an unlabelled aneurysm clip and an available clip specimen, it is possible to perform this test based on the current ASTM F2052 guideline [37].

There is no publication in the literature to substantiate that no MR unsafe aneurysm clips were made after a certain date. However, Shellock states in 1998 that since that period no aneurysm clips have

been produced that pose a risk to patients in the MRI environment [30]. However, previously produced (possibly unsafe) aneurysm clips may have been implanted at a later date.

The MRI safety of aneurysm clips is determined by the manufacturer and tested at one or more field strengths. Although the MR conditional indication as determined at a certain magnetic field strength or with a certain scanner model does not automatically apply to other field strengths or scanners, Shellock has shown that the current aneurysm clips for which an MR conditional classification applies at 1.5 T do not show excessive torque or displacement in a 3 T scanner [38].

2. <u>Risk of implant heating due to interaction with the RF field.</u> From a physics point of view, the risk of heating tissue around a cerebral aneurysm clip can be expected to be negligible due to the short (non-resonant) length of the clips. The wavelength of RF waves at the resonant frequency in water in clinical scanners is significantly greater [38]. Watanabe et al. measured a temperature difference of less than 1 °C in clips made of titanium and Elgiloy at 3 T in the most unfavourable position; at the side of the bore [17]. Watanabe et al. refers to wavelengths of meters in air at 3 T, while the effective wavelength *in vivo* is lower, of the order of 17 to 90 cm at 3 T depending on the type of tissue.

Typical heating as reported by the manufacturer Aesculap in a Yagarsil aneurysm clip is 1.8 °C in titanium and 2.5 °C in Phynox aneurysm clips at 3 T after 15 min of scanning. Manufacturers classify 154 of 349 aneurysm clip models as MR conditional, with a maximum whole body SAR of 2 W/kg [34]. These measurements are based upon the ASTM standard F2182 [39], and for older implants on previous versions of this standard.

However, the manufacturers often report the maximum temperature increase as measured in the gel phantom setup, not the additional temperature increase due to the aneurysm clip alone. Given the test conditions where the gel heats up already without the implant, this kind of reporting overestimates the actual temperature increase due to the clip. Furthermore, additional cooling occurs *in vivo* due to the blood flow in the vessel from which the aneurysm is clipped.

Based on these data and arguments, the opinion of the authors is that the heating *in vivo* as a result of a cerebral aneurysm clip will remain below 1 $^{\circ}$ C during clinical MR scans at 3 T and below and that therefore no additional SAR restrictions are required during such scans.

- 3. Risk of vibration or induction of currents by the oscillating magnetic field gradients applied for the spatial encoding of the MRI signal. The magnitude of these eddy currents depends on the surface area enclosed by a loop-current within the implant. This risk can be expected to be negligible due to the small surface area of the aneurysm clip, and due to the high frequency of the vibrations they won't result into an effective torque [40]. In theory, vibrations could lead to sensory effects. However, we found no indications for this for aneurysm clips in the literature, neither in our clinical experience.
- 4. <u>Presence of artefacts in the MR image.</u> Due to local perturbation of the static magnetic field, the presence of an aneurysm clip will lead to image artefacts. The size and shape of these artefacts partly depends on the size, shape, type of material and spatial orientation of the clip, but also on the field strength of the MRI scanner and the type of MRI sequence.

Several publications report about artefacts in the vicinity of aneurysm clips. Brothers et al. concluded that in patients using Sugita-clips (made of cobalt-chromium alloy) and Drake-tourniquets, the diagnostic information obtained with MRI appears to be more valuable than that obtained with CT in the same patients [41]. Artefacts around titanium aneurysm clips (0.4 to 1.2 cm²) appear to be about one third of the size with respect to those caused by 'conventional clips' made of cobalt-chromium alloy (1.0 to 3.6 cm²) [42]. A study comparing a titanium aneurysm clip with clips

made of Phynox, Elgiloy, MP35N, NiCoCrMo and CrNiMo showed artefacts around the titanium clip that were 2.5 to 5 times smaller than those around the other materials (0.7 cm² and 1.8 to 3.9 cm² respectively) [13]. A case study of a patient who underwent an MRI scan with a ferromagnetic aneurysm clip showed that this clip produced such image artefacts that the images of a large part of the brain were virtually worthless for diagnosis [19].

Metal artefacts are unavoidable, but a number of measures can be taken to reduce the adverse impact of metal artefacts: choosing lower field strength (1.5 T instead of 3 T), applying spin echo instead of gradient echo techniques, shortening echo time, applying techniques for reduction of metal artefacts, swapping frequency and phase coding direction or opting for a smaller voxel size or higher readout bandwidth [43].

When the area of interest is close to the aneurysm clip, or when the artefact is expected to be large, consideration should be given to whether MRI has sufficient diagnostic value.

- 5. <u>Risk of forces due to the Lenz effect during rapid movement of</u> <u>conductive implants in the static magnetic field of the MRI scanner.</u> Due to the size of the implant this risk is negligible at current standard 1.5 T and 3 T systems [32,40].
- 6. <u>Risk of interference with implant function</u>. The only risk associated with aneurysm clip function is displacement or rotation; a risk that has already been addressed.

As the only significant risks are related to the ferromagnetic properties of the aneurysm clip, the probability that an unknown aneurysm clip is ferromagnetic is the main question to address for each individual case.

3.5. Considerations for unknown aneurysm clip model

When the model of the aneurysm clip cannot be determined, it can be taken into account that the chance of finding someone in the general population with a ferromagnetic aneurysm clip is very small: a large retrospective study showed that 0.03% of the referred outpatients had a ferromagnetic aneurysm clip [44].

In the case of an unknown model of aneurysm clip, a conservative risk assessment can be pursued and, as a precaution, it can be decided not to perform an MRI examination [1]. However, it should be taken into account that withholding diagnostics by means of MRI can have negative consequences for the patient as well, and therefore both aspects should be weighed [2].

Based on the literature and previous considerations and Table 3, the risk of patient damage when using MRI in the presence of an unknown cerebral aneurysm clips has been estimated as an expert opinion, depending on the year and hospital of implantation of the clip (Table 4). This information can be used to perform a risk–benefit analysis for an individual patient. For patients who have an aneurysm clip implanted outside the Netherlands, it is assumed that in countries and hospitals with a standard of healthcare comparable to the Netherlands, a similar risk assessment has been pursued with regard to model of aneurysm clip implantations, and a higher risk elsewhere.

4. Recommendations

The recommendations are based on a combination of scientific evidence together with a national expert opinion. To investigate whether a patient with an aneurysm clip can undergo an MRI exam, a stepwise approach is advised, following the decision scheme (Fig. 1):

1. Determine the year and hospital of implantation of the cerebral aneurysm clip in a patient with an MRI indication. This can be done on the basis of the patient's traceable data, such as the operation report, electronic health record (EHR) or by asking the patient or his/ her physician.

Table 4

Probability of damage from unknown cerebral aneurys	sm clip.
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Hospital Implantation	Year of implantation	Probability of damage from unsafe aneurysm clip in $MRI^{*,\#}$
Netherlands ^{**}	2000 and later 1990–1999 1989 and earlier	unlikely unusual to rare ^{***} to be expected
Elsewhere	1995 and later 1994 and earlier	unusual to be expected

As estimated by the authors based on a survey among all Dutch hospitals in the Netherlands.

 $^{\ast}\,$ This only applies to horizontal closed bore whole body MRI systems of 1.5 T and 3 T.

** The Netherlands or in a country/hospital with an equivalent level of health care.

*** This is based on the fact that before all the aneurysm clips were nonferromagnetic, most of the aneurysm clips produced since the nineties were not ferromagnetic, and that a ferromagnetic aneurysm clip will not always cause damage.

[#] Words of estimative probability are used to stress the estimate character of this table. In the methods section a quantitative range is coupled to these words.

- a. If the year of implantation is 2000 (Table 4) or later and the aneurysm clip is implanted in the Netherlands (*or in a country/ hospital with an equivalent level of health care*), MRI can be performed and the aneurysm clip is considered MR conditional for 1.5 and 3 T horizontal closed bore whole body MRI systems'.
- b. If implantation took place in the Netherlands before 2000, determine on the basis of Table 2 whether the aneurysm clip is unlikely to be ferromagnetic. If so, the aneurysm clip is considered MR conditional for 1.5 and 3 T horizontal closed bore whole body MRI systems.
- c. In all other cases, determine the model of aneurysm clip and check Table 1 to see if the aneurysm clip is MR unsafe or not. If the aneurysm clip is MR unsafe, no MRI examination should be performed. If the aneurysm clip model is not in Table 1, the clip is considered MR conditional for 1.5 and 3 T horizontal closed bore whole body MRI systems.

If the clip model information cannot be retrieved:

- Investigate whether the patient has previously undergone MRI of the head region at a horizontal closed bore whole body MRI system after aneurysm clip implantation. If there has been such a previous MRI:
 - a. Ensure that the MR safety expert assesses the images and evaluates the effect, taking into account the applied field strength and model of MR scanner [4,5]. Get information whether the patient experienced any physiological effects that may relate to the aneurysm clip during or after the MRI exam. Based on artefact size and applied MR sequence, an estimate can be obtained on the degree of ferromagnetism of the aneurysm clip. If the aneurysm clip is considered unsafe, no MR examination is allowed.
 - b. If artefacts may lead to a non-diagnostic scan, the MRI examination should not be performed.
- 3. When the model of aneurysm clip cannot be determined, it is advised to estimate, based on the hospital and the year of aneurysm clip implantation with Table 2, 3 and/or Table 4 and, when available, information of a previous MRI exam, the probability of injury to the patient by MRI. In consultation with the radiologist and the patient a risk–benefit analysis between the probability of injury and the importance of diagnosis should be made.
- 4. If it is unclear whether the aneurysm clip is MR non-ferromagnetic, but an MRI examination is performed based upon the risk–benefit analysis, then:

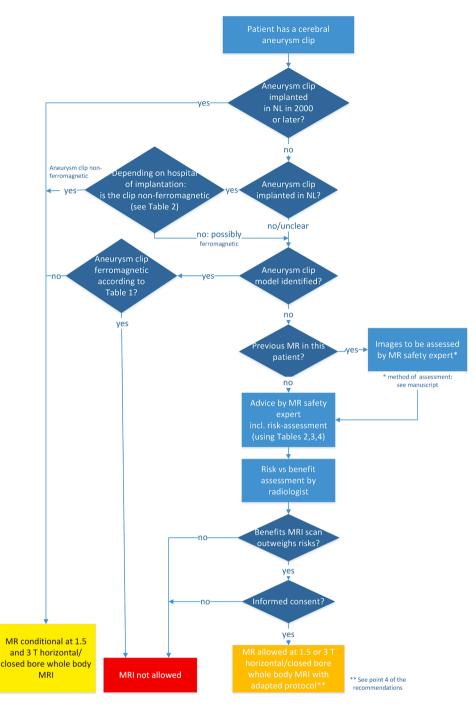


Fig. 1. Flowchart with decision tree for MRI examination in patient with a cerebral aneurysm clip, with references to Tables numbers in this manuscript (which differ in numbering from the Dutch guideline).

- a. inform the patient and ask his/her consent (according to local procedures for a medical informed consent);
- b. scan at a 1.5 T horizontal closed bore MRI system if the probability of a ferromagnetic aneurysm clip is greater than 'rare';
- c. if possible, keep the patient's head centred in the opening of the scanner, not at the edges of the bore opening. In the centre of the MRI bore opening the forces are smaller than off-centre in the opening. 'Feet first' patient positioning is preferable when possible for all scans except for head imaging. The spatial B_0 stray field of a horizontal closed bore superconducting 1.5 T whole body magnet is in first order symmetric in the z-direction except for the sign of the B_z component. Therefore, with both 'feet first'

and 'head first' positioning the patient's head will be at a location with an equal magnitude of the spatial field gradient during imaging and thereby an equal magnitude of the displacement force. However, 'head first' positioning is less preferable as the patient's head will always pass the region of maximum torque at the bore centre, and the displacement force will act in two opposite directions at both sides of the bore.

- d. support/fix the patient's head to prevent head motion;
- e. do not scan on an open-bore MRI system.

The manuscript is based upon work for a recently developed guideline by the Dutch Association of Medical Specialists [3]. An English translation appeared in 2021. This guideline was reviewed by the involved Dutch (scientific) associations, agencies and (patient) organizations. The final version was authorized in 2019 by the FMS, and more specifically by the Society for Medical Physics of the Netherlands (NVKF), Radiological Society of the Netherlands (NVvR), the Netherlands Society for Neurosurgery (NVvN) and the Dutch Society for Medical Imaging and Radiotherapy (NVMBR) (representing the MR technologists).

In drafting this manuscript small improvements were made. These will be translated into the Dutch guideline in a next update.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Authors' contribution

All authors contributed to the guideline conception and design. Acquisition of data and analysis and interpretation of data was performed by Lavini, van der Zwan, Muller, Stam, Kuijer and Hofman. The first drafting of this manuscript was written by Hofman. Critical revision was performed by all authors, and they all approved the final manuscript.

Ethical approval

IRB approval is not required for the review.

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