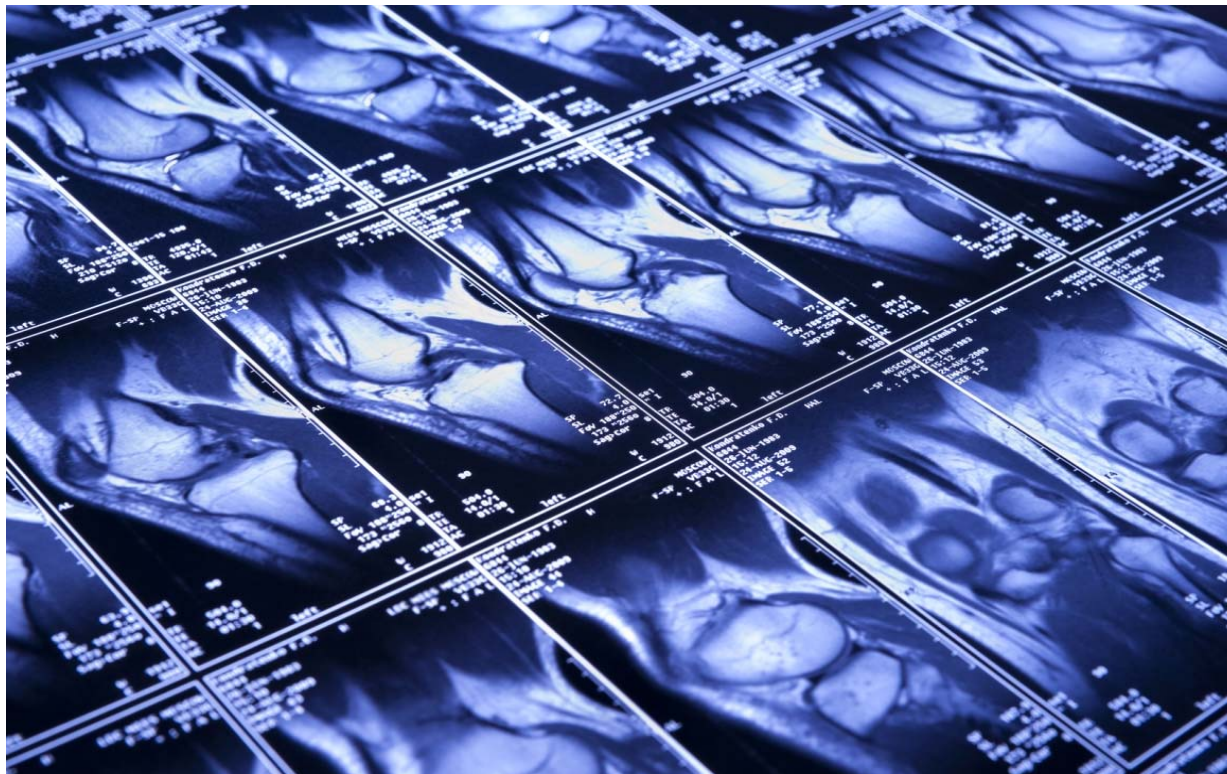


EXTREMITY-ONLY MRI



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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
AHRQ	Agency for Healthcare Research and Quality
BELMIP	Belgian Medical Imaging Platform
eMRI	Extremity-only MRI
ENT	Ear – nose – throat
FANC	Federal Agency for Nuclear Control
FOV	Field-of-view
FPS	Federal Public Service
HAS	Haute Autorité de Santé
IMA	Intermutualistic Agency
MRI	Magnetic resonance imaging
NIHDI	National Institute for Health and Disability Insurance
RCT	Randomized controlled trial
RF	Radio frequency
RIZIV – INAMI	Rijksinstituut voor Ziekte- en Invaliditeitsverzekering – Institut National d'Assurance Maladie-Invalidité
SNR	Signal-to-noise ratio
SR	Systematic review
T	Tesla



■ SCIENTIFIC REPORT

1 BACKGROUND AND RESEARCH OBJECTIVES

The dedicated extremity-only MRI (eMRI) systems were designed to visualize the limbs by means of magnetic resonance. The indications are disorders that are limited to the peripheral parts of the limbs (e.g. knee, elbow, ankle, wrist, hand, foot). Disorders which potentially affect parts of the limbs but which at the same time might affect other structures as well require imaging on a whole body MRI system. An eMRI device is cheaper than a whole body MRI. The eMRI could be less frightening for claustrophobic patients. The position might be more comfortable for patients and the noise level of the machine is lower. There are extremity-only devices with a high and low magnetic field strength, which has an impact on the quality of images.

About all hospitals currently use whole body MRI scanners to image extremities. These devices generate good-quality images and are primarily used for indications other than the imaging of extremities. In view of the waiting lists that exist in Belgium, the Federal Public Service Health, Food Chain Safety and Environment questions to what extent limb scans using whole body MR scanners can be replaced by or complemented with (high-field strength) extremity-only MRI scanners and what the effects would be in terms of quality, efficient use of resources, health-economic effects, etc..

Starting the project, the research scope was determined and several research questions were formulated: Which extremity-only techniques are available? What is the Belgian situation for (e)MRI? What are the potential (dis)advantages and consequences of implementing eMRI-systems? What is the available evidence for different indications? How is the real-life experience with eMRI in other countries? What are the health-economic consequences of introducing eMRI in Belgium? What are plausible financing mechanisms for eMRI in Belgium?



The research team looked for evidence and contacted several experts. Based on an interim evaluation of available evidence, expert opinions and the report of the Belgian College for Radiology¹ (see further), the following research questions were retained and covered in the report.

- What extremity-only techniques are available? (Chapter 2)
- What is the Belgian situation (number of MRIs and legal context of (e)MRI)? (Chapter 3)
- What are the potential (dis-)advantages and consequences of implementing eMRI-systems? (Chapter 4)
- What is the available evidence supporting eMRI for different indications? (Chapter 5)

In Chapter 6, we further discuss two interesting Belgian reports providing further insight in the current situation of medical imaging in Belgium.

2 TECHNOLOGY DESCRIPTION

2.1 An MRI system and its components

Since its introduction in the early 1980s, magnetic resonance imaging (MRI) has become essential for patient management. Indications for MRI and CT-scan are guided by specific characteristics inherent to the imaging technique. The list of MRI indications includes many musculoskeletal indications located in the arms or the legs. An important advantage of MRI over CT is the absence of ionising radiation.

An MRI system consists of five major components: a magnet, a magnetic gradient system, a radio frequency (RF) coil system, a receiver, and a computer system.² The field strength of the magnet, expressed in Tesla (T), is a key factor in determining the quality of an MRI image. However, the overall quality of the MRI images is determined by the interplay of a number of MRI parameters, and not by the field strength of the magnet alone. The role of each of these components should be considered when evaluating the possible advantages and disadvantages of one specific subtype of MRI system. It should also be kept in mind that certain parameters chosen by the MRI operator, e.g. the chosen radio frequency sequence, further determine the quality of the images. For a more detailed description of the technique, interested readers are referred to Chung et al. (2011), the HAS (Haute Autorité de Santé) report 2012 or to existing standard works on MRI imaging.^{2,3}

The imaging using MRI, including MRI of joints, may be improved using gadolinium. This is however not addressed in this study.



2.2 MR field strength: definitions

Magnetic field strength of clinical MR scanners can vary considerably. Scanners are often categorised as low-field, mid-field or high-field devices. In the literature, the borders between the different categories are somewhat vague, and can vary slightly.²⁻⁴

According to the expert panel consulted for the present report (see colophon), the following definitions are mostly used in Belgium:

- Low-field ($\leq 0.5T$)
- Mid-field ($> 0.5T - < 1.5T$)
- High-field ($\geq 1.5T$)

MR field strength is a key factor in determining the quality of an MRI image. In general, higher field strength improves the signal-to-noise ratio (SNR), which results in improved image resolution. SNR, contrast, and resolution increase almost linearly with field strength. The extra SNR afforded by higher field strength can be used in several different ways: to reduce acquisition time at a given spatial resolution (and lowering the incidence of motion artifacts) or to improve spatial representation at a given acquisition time. Noise can be reduced relative to signal by increasing voxel volume, e.g. by increasing the field of view or increasing the slice thickness. However, higher voxel volume may cause volume-averaging signal abnormalities that make lesions more difficult to detect.^{3,5,6}

As a result, for low-field MRI devices acquisition time tends to be longer and image resolution lower as compared to devices with higher field strength.^{3,5,6} Whether low-field or mid-field MRI devices can provide sufficient diagnostic information or not might depend on the clinical question for which the MRI exam is performed. Diagnostic evaluation studies are required to clarify this issue (see also chapter 5).

Although MR field strength is a very important factor in determining the quality of the images, it is not the only one. For example, the RF pulse sequences should be adapted to the clinical diagnostic question. Further, the gradient system, the coil design, the chosen data acquisition parameters and the computer program processing the raw image data, all contribute to the final image quality, and to the clinical diagnostic value of the MRI scan. Although standardized protocols are in use for routine scanning, individual tailoring is necessary to yield optimal diagnostic performance for specific clinical queries.^{2, 3} Especially in more complex indications, imaging parameters need to be adjusted by the radiologist or technologist, and a longer acquisition time might be necessary to obtain high-quality imaging. This will thus lower patient throughput, a notion to keep in mind with respect to recommendations concerning MRI financing.

2.3 Whole body and extremity-only MRI (eMRI)

At present, most clinical MRI evaluations in Western countries are performed using whole body MRI scanners with a field strength of 1.5 to 3.0 Tesla. However, since the 1990s, dedicated extremity-only scanners (also called extremity-only MRI or eMRI) have been developed, to provide MR images of the arms and legs using smaller magnets, reducing construction and installation costs (see Figure 1). These devices would also be less frightening and more comfortable for patients (see also chapter 4).

Two major factors determine the intrinsic differences between the currently commercially available eMRI devices.

The first factor is the field strength. Originally, eMRI scanners were low-field or mid-field devices, but high-field eMRI systems became available some years ago. The importance of the field strength in defining the MRI image quality has been discussed in the previous paragraph (see 2.2).



The second factor is the configuration of the eMRI bore. One of the main characteristics of the bore is whether it is open or closed. The configuration of the bore determines the maximal field-of-view (FOV), i.e. the surface that can be explored. For each diagnostic indication, the minimally required FOV expressed in centimetres is different. Therefore, the FOV is a determinant of the diagnostic indications that can be dealt with on the equipment. Based on the configuration of their bore, the available eMRI devices differ in the type and number of extremity indications that they can deal with. Especially some closed bore eMRI devices have a limited range of extremity indications they can deal with, taking into account their maximal FOV.

Further it should be noted that additional options for eMRI devices have been developed, e.g. the possibility to perform images while a joint or a part of the body is under loading stress; this option also exists for whole body MRI devices.²

The next paragraph presents a brief overview of the most important clinical MRI systems developed commercially:

- Low-field ($\leq 0.5T$) or Mid-field ($>0.5T - <1.5T$):
 - extremity-only MRI, closed or open system: hand-wrist-elbow-foot-ankle-knee
 - previous type, open system, plus: under loading stress if vertically placed (more expensive, larger than previous)
 - whole body MRI, closed or open system (including: under loading stress: if vertically placed or loading stress by compression)
- High-field ($\geq 1.5T$):
 - conventional whole body MRI, closed system (including: under loading stress by compression)
 - extremity-only MRI, closed or open system
 - whole body MRI, open system (including: under loading stress: if vertically placed or loading stress by compression)

Interventional and intra-operative MRI, can be low-, mid- or high-field.

Interventional and intra-operative MRI devices will no further be discussed in this report. Also not discussed are developments whereby MRI is combined with additional imaging systems such as a PET scan.

Figure 1 – Example of a extremity-only MRI system



Source: Bigstock



3 (E)MRI IN BELGIUM

3.1 Legal status

In Belgium, it is obliged by law to install MRI-units in hospitals. In order to operate an MRI-unit, a hospital has to meet certain criteria/norms defined by the federal government to qualify for subsidies from the government and reimbursement by third party payers. In addition, the federal government also restricted (“programmed”) the total number of MRI-units for each region and the number of MRI scanners per unit.⁷

Extremity-only MRI scanners are included in the general definition of MRI scanners (art. 1, 3° Koninklijk besluit van 25 oktober 2006⁷).⁸ Consequently regulations on programming and criteria also apply to eMRI. Former legislation limited the installation of an eMRI to units meeting all criteria and with a whole body MRI scanner already available.⁹ The European Commission requested to remove any differentiation between eMRI and whole body scanners in programming and criteria/norms, based on the argument of unfair competition. The National Council for Hospital Services, however, argued that the difference in use between whole body MRI and eMRI justifies the exceptions for eMRI.¹⁰ Since February 2003 however, the rule was abolished (art. 51 Wet 27 april 2005).¹¹ Therefore, there is currently no different legal status for eMRI compared with whole body MRI.

3.2 General situation

In 2012, there were 109 approved MRI units in Belgium. A large part has been approved between 2008 and 2009 (Table 1 and Figure 2). There were also a number of non-approved units (e.g. 4 in 2008).¹² To our knowledge, there are no eMRI systems in clinical routine use in Belgium.

Figure 2 – Evolution of approved MRI units in Belgium

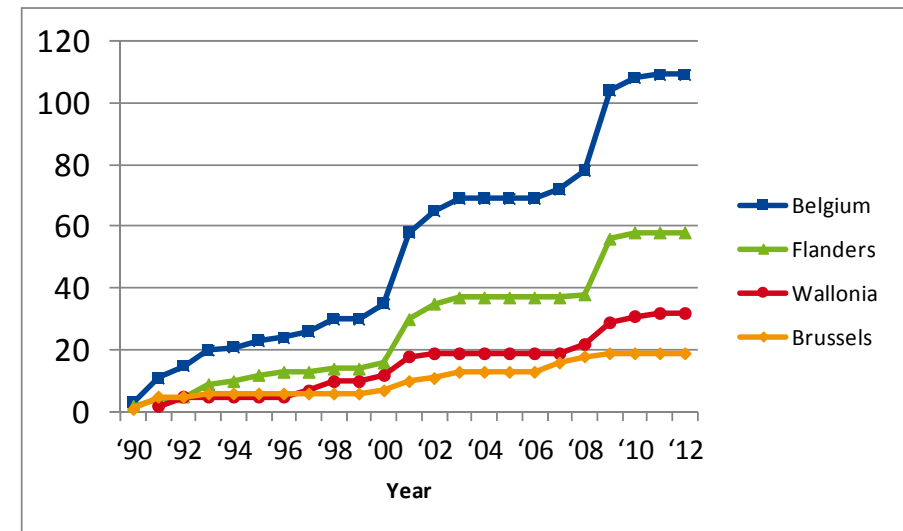


Table 1 – Number of approved MRI units in Belgium (1990-2012)

Year	'90	'91	'92	'93	'94	'95	'96	'97	'98	'99	'00	'01	'02	'03	'04	'05	'06	'07	'08	'09	'10	'11	'12
Brussels	1	5	5	6	6	6	6	6	6	6	7	10	11	13	13	13	13	16	18	19	19	19	19
Wallonia		2	5	5	5	5	5	7	10	10	12	18	19	19	19	19	19	19	22	29	31	32	32
Flanders	2	4	5	9	10	12	13	13	14	14	16	30	35	37	37	37	37	37	38	56	58	58	58
Belgium	3	11	15	20	21	23	24	26	30	30	35	58	65	69	69	69	69	72	78	104	108	109	109

Source: service 'Data Management' from 'DG Health' of FPS Health, Food Chain Safety and Environment



The financing of MRI can be split into two broad categories. First, there is fixed yearly financing, for the investment and operational costs (excluding the cost of radiologists). As legally stipulated, part A3 and B3 of the hospital budget are supposed to cover almost all MRI related costs except for the radiologist costs. Second, there is a mixed system of fee-for-service (fee per MRI examination) and lump sum financing (consultancy lump sum per inpatient stay and a lump sum per inpatient admission) intended to cover the cost of radiologists. In reality, the radiologist's fee also covers part of the other costs (if A3 and B3 are insufficient). For more information on the financing of MRI, we also refer to KCE report n°106 (chapter 9 'current financing of MRI').¹²

There are Belgian guidelines containing recommendations which are intended to help physicians make optimal use of medical imaging and to limit the harmful effects caused by inappropriate use of X-rays and CT scans. These guidelines are available under the following link: www.health.belgium.be/richtlijnen-medische-beeldvorming; www.health.belgium.be/recommandations-imagerie-medicale.

The included imaging techniques do not distinguish between eMRI and whole body MRI.

The fact that there exist waiting lists for MRI evaluations in Belgium has been generally acknowledged by many professionals and representatives of the administration for several years already. Unfortunately, figures on the length of waiting lists for MRI, or on the (average) duration of time before MRI examinations can be performed, are not available.

Table 2 – Belgian data on MRI evaluations (2000-2012)

MRI Evaluations in Belgium	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
MRI all indications: N cases	220.534	328.355	365.364	411.332	447.805	460.306	484.815	509.994	564.987	668.922	717.067	772.215	827.737
MRI extremities: N cases	49.088	76.180	86.235	98.160	107.720	112.812	118.003	125.699	144.559	176.794	193.059	210.132	223.832
MRI extremities: % of all indications	22,3%	23,2%	23,6%	23,9%	24,1%	24,5%	24,3%	24,6%	25,6%	26,4%	26,9%	27,2%	27,0%

Source: based on NIHDI data

3.3 Belgian data on MRI evaluations of the extremities

Data obtained from the National Institute for Health and Disability Insurance (NIHDI or RIZIV/INAMI) shows that the proportion of MRI evaluations of the extremities as compared to the total of all MRI evaluations was 27% in 2012; this proportion has slightly increased over the years (see Table 2). Data differentiating for the type of MRI device used to perform the MRI evaluation are not available. It should be kept in mind that this data describes the actual prescription and reimbursement of MRI evaluations, and does not allow for concluding on the appropriateness of these MRI evaluations. Therefore this data might be an over- or underestimation of the real evidence-based need for MRI imaging in the Belgian population.



4 POTENTIAL (DIS)ADVANTAGES OF (E)MRI

One of the research questions concerns the possible advantages and disadvantages of different MRI devices: conventional whole body MRI, high-field extremity-only MRI, low-field extremity-only MRI.

A quick scan of the scientific literature learned that it would not be possible to answer this question based on a literature evaluation. Therefore it was decided to consult Belgian experts. This happened in an informal way by visiting the MRI center of two university hospitals (UZ Brussel, UZ Gent) and by discussing a draft version of the report with a group of experts (see colophon). This was completed with information obtained from (inter)national experts in this domain (E.Oei, D.Tessier-Vetzel, and J Gielen, see colophon) who acted as validators and approved the final version of the report. An overview of the possible advantages and disadvantages can be found in Table 3.

The current medical interest of the consulted Belgian experts for low-field eMRI was low due to the lower quality of images. There was also little interest in high-field eMRI; according to the experts the algorithms deserve further optimization. However, the most important reasons not to invest in eMRI are the restriction for MRI units in general and, according to the consulted Belgian experts, the limited number of indications for eMRI. If a centre can invest in MRI, then whole body MRI is preferred since it can be used for more indications. University centres also see more opportunities for research. The affordability of eMRI versus whole body MRI was not a determining factor. The experts stated that eMRI theoretically could be a justified investment if the volume of eMRI indications would be sufficient to run an eMRI, but of course all the potential (dis)advantages of (e)MRI (e.g. quality concerns) should be taken into account as well. According to the Belgian experts consulted, only few large MRI centres would have a sufficient number of patients with an appropriate indication to justify the investment in a dedicated eMRI system.

This general remark is also related to an important issue raised by one of the international experts. Experts consulted by the “Haute Autorité de Santé” (HAS) in 2012 (HAS report 2012, see also chapter 5) estimated that the available eMRI devices with a closed bore would not be suitable to perform 30 to 50% of all MRI evaluations of extremities in France, due to the limitations in field-of-view inherent to the configuration of their bore.³ This would further limit the usefulness of this type of eMRI devices and add to the difficulties in planning the right MRI evaluations on the right MRI device (eMRI for some extremity indications, whole body MRI for other extremity indications).

One of the main arguments to prepare the present report was that eMRI could possibly help to reduce the existing waiting lists for MRI. This hypothesis was challenged. Several experts noticed that patients with indications for which eMRI would suit are currently often used to “fill the gaps” in the schedule of the whole body MRI. However, this depends on the volume of eMRI indications and may be centre-specific. Furthermore, if an extra eMRI system would be installed, it was feared by some experts that this would stimulate performing eMRI in indications that are not evidence based, without a decrease in the use of the whole body MRI.


Table 3 – Potential (dis)advantages of extremity-only versus conventional whole body MRI

	Advantages	Disadvantages
Conventional whole body MRI	<ul style="list-style-type: none"> • Can be used for all indications. • (ultra-)high-field MRI is often used for research purposes. • 3T MRI is preferred for specific indications of hand and wrist. 	<ul style="list-style-type: none"> • Can cause anxiety, claustrophobia. • Waiting lists exist in Belgium. • Purchasing price and maintenance cost higher than for extremity-only MRI. • Less comfortable positioning of the patient examined for specific joints, elbow and wrist, in prone or lateral position leading to motion artefacts. • In whole-body MRI, specific coils do not exist for some joints (e.g. for the elbow).
Extremity-only MRI (high-field)	<ul style="list-style-type: none"> • Comparable image quality in comparison with whole body MRI if similar magnetic field strength (e.g. 1.5T) combined with similar peripheral equipment (gradient system...), and if field-of-view sufficient for diagnostic indications that will be dealt with. • Better affordability: lower purchasing price and maintenance cost. • Easier to use (~personnel requirements). • Less heavy and requires less space. • More comfortable for the patient (position, less noise). • Anxiety and claustrophobia less likely. • Introduction in Belgium of eMRI might allow for quicker diagnosis and treatment because of easier access (no waiting times). • Could also reduce waiting times for whole body MRI and thus allows more efficient use of whole body MRI. 	<ul style="list-style-type: none"> • Might not be suitable for all diagnostic extremity indications, depending on the bore configuration (field-of-view). • For some eMRI devices, purchasing price and maintenance cost are nearly comparable to whole body imaging equipment. • Due to the relatively limited bore opening in some devices, positioning of the knee and ankle may be easier in a whole body MRI (due to problems with e.g. a fully stretched knee or ankle in plantar flexion in post-traumatic situation). • Might induce overconsumption because of ease of access, and might therefore cause increasing costs. • Risk of lower quality/ availability of expertise if performed outside of MRI unit (eg emergency department). • Not available as 3T.
Extremity-only MRI (low-field)	<p>Versus high-field (e)MRI:</p> <ul style="list-style-type: none"> • Affordability: lowest purchasing price and maintenance cost. • Protection for magnetic field is less of an issue. 	<p>Versus high-field (e)MRI</p> <ul style="list-style-type: none"> • Lower quality of images. Not as sensitive as high-field MRI. • Requires more time to provide good images (lower signal-to-noise ratio). • Might not be suitable for all diagnostic extremity indications, depending on the bore configuration (field-of-view).



5 AVAILABLE EVIDENCE FOR EMRI

5.1 Introduction

5.1.1 Research question

In most Western countries, the largest part of clinical MRI evaluations are nowadays performed on whole body MRI scanners with a field strength of 1.5 to 3.0 Tesla. In Belgium, to our knowledge, no eMRI devices are currently in use. The main question for this report is whether these devices could take over current extremity evaluations performed on whole body MRI scanners, thereby reducing in Belgium the existing waiting lists for whole body MRI scanners.

The main research question for the literature review concerns the diagnostic efficacy of low-, mid-, or high-field extremity-only MRI.

All potential diagnostic indications for an MRI extremity evaluation in all patient populations are included. Excluded are interventional or intra-operative evaluations.

Since the main question is whether eMRI could take over extremity evaluations currently performed on whole body MRI scanners, special attention will be given to the evidence directly comparing diagnostic efficacy between eMRI and conventional high-field ($\geq 1.5T$) whole body MRI.

5.1.2 *The hierarchical model of efficacy of diagnostic tests by Fryback and Thornbury*

In 1991, Fryback and Thornbury first described the different steps that should be considered when evaluating the clinical value of diagnostic imaging.¹³ Since then, their hierarchical model of efficacy has been generally accepted in conceptual thinking on the contribution of diagnostic tests in general to the patient management process.¹⁴

The model can be used as an organizing structure for appraisal of the literature on efficacy of a diagnostic test. Demonstration of efficacy at each lower level in this hierarchy is logically necessary, but not sufficient, to assure efficacy at higher levels. The model comprises:

- Level 1: technical quality of the test;
- Level 2: diagnostic accuracy, sensitivity, and specificity of test interpretation;
- Level 3: does the test result produce change in the referring physician's diagnostic thinking;
- Level 4: effect of the test on the patient management plan;
- Level 5: effect of the test on patient outcomes;
- Level 6: societal costs and benefits of the diagnostic test.

In the literature review below, the model of Fryback and Thornbury was used to conclude on the overall value of extremity-only MRI as a tool in clinical diagnostic imaging.

5.2 Methodology

Only a limited literature review was performed in July and August 2013.

First, a search was conducted for existing systematic reviews (SRs) or meta-analyses, for which the following databases were included:

- Medline (<http://www.ncbi.nlm.nih.gov/pubmed>);
- The Cochrane Database of systematic reviews (<http://www.cochrane.org>).

No time restrictions were involved. For the search date, search strategy and selection of the publications, see Appendix 1.1.1.

Additionally, relevant websites were searched for guidelines based on systematic reviews; for a list of these websites, the search date, search strategy and selection of the publications, see Appendix 1.1.2.

Systematic reviews were accepted if they were in English, French, Dutch or German, and if searched databases were mentioned; narrative reviews were excluded. The SRs had to include prospective or cross-sectional diagnostic accuracy studies using a gold standard test; or randomized



controlled trials (RCTs). Only SRs having performed a quality appraisal of the included studies and/or including data extraction tables were accepted.

On the accepted SRs, a quality appraisal was performed using the AMSTAR checklist (http://amstar.ca/AMSTAR_Checklist.php); the studies are discussed below (see section 5.3). Three items of this checklist were considered key for labelling a review as high quality (items 3-7-9).

After the search for SRs, a search for primary studies published after the most recent search date of the included reviews was done in Medline.

Since the most recent included SR (see further) was based on a literature search up to 2/2012, the search for primary studies was limited to 2012-2013. For the search date, search strategy and selection of the publications, see Appendix 1.1.3.

Primary studies were accepted if they were in English, French, Dutch or German, and if it were RCTs directly comparing diagnostic efficacy between eMRI and conventional high-field ($\geq 1.5T$) whole body MRI. RCTs evaluating the diagnostic properties of high-field eMRI ($\geq 1.5T$) were accepted even if no direct comparison to conventional high-field whole body MRI was made. A quality appraisal using the Cochrane Collaboration's tool for assessing risk of bias was planned for the retained RCT; however, no RCTs were accepted (see further).

The model of Fryback and Thornbury was used to formulate the overall conclusions.

For the primary studies included in the reviews, critical evaluation as described in the SRs involved methodological study parameters, e.g. selection of a representative study population, utilisation of a valid gold standard, reporting of drop-outs etc.. However, the applied MRI methodology, including pulse sequences utilized, pulse sequence parameters, spatial and slice resolution, etc. was also carefully evaluated, because technical imaging parameters can dramatically change the appearance of one specific disease condition.

5.3 Results

Two literature reviews were found and accepted:

- report of the Agency for Healthcare Research and Quality AHRQ, USA by Chung et al. (2011)² on emerging MRI technologies for imaging musculoskeletal disorders under loading stress. This review contains one chapter fully dedicated to the use of extremity-only MRI for all types of indications, based on a broad search strategy not limited to conditions under loading stress;
- report of the Haute Autorité de Santé HAS, France (2012)³, on the diagnostic use of MRI equipments with a field strength of ≤ 1 Tesla for osteo-articular evaluation of the extremities.

The results of the AMSTAR checklist rating can be found in Appendix 1.2.

In the search for primary studies (2012-2013), no RCTs corresponding to the predefined selection criteria could be found.

5.3.1 AHRQ report 2011

In the AHRQ report 2011, a systematic search was performed in the Medline (Ovid) database from 1975 to September 2010 including evidence on dedicated extremity MRI.² No restrictions were made on the field strength, but it turned out that all of the 36 included publications evaluated ≤ 1 Tesla systems. No quality appraisal of the included studies was performed, but evidence tables were provided. Based on the AMSTAR checklist rating, the AHRQ report 2011 was labeled as a low quality review (see also Appendix 1.2).

The reviewed studies were conducted among a variety of patient populations, the most common conditions were rheumatoid arthritis (15 publications), extremity injuries (5 publications) and osteoarthritis (4 publications). None of the included studies evaluated eMR imaging under loading stress.

Of the included studies, 1 was an RCT (reported in 4 publications; 3 out of these 4 publications were included in the AHRQ report 2011). The RCT, including 500 patients, compared plain radiographs followed by eMRI imaging (0.2T) versus plain radiographs alone for the diagnosis of acute extremity injuries (wrist, knee or ankle).¹⁵⁻¹⁸ No direct comparison between eMRI and conventional whole body MRI was made. The primary analysis of the trial reported on clinical effectiveness of eMRI (time-to-completion of



the diagnostic workup, number of additional diagnostic procedures during follow-up, quality of life, number of days to convalescence etc.) and costs (medical and nonmedical expenses as well as societal costs, in the context of the Netherlands). Compared with plain radiography, eMR imaging in patients with acute wrist or ankle injuries was neither cost saving nor effective in expediting diagnostic work-up or improving quality of life. In patients with knee injuries, the eMRI examination shortened the time to completion of diagnostic work-up, reduced the number of additional diagnostic procedures, improved quality of life in the first 6 weeks, and might reduce costs associated with lost productivity. Further, the trial concluded that a short MRI imaging examination following radiography in the initial evaluation of patients with acute wrist, knee or ankle injury had additional value in prediction of treatment need, but did not have value in identification of patients who could be discharged without further follow-up.

Of the other studies included in the AHRQ report 2011, 4 cross-sectional studies described a comparison of eMRI versus conventional 1.5 T whole body MRI; 3 studies dealt with rheumatoid arthritis and 1 with acute and chronic knee lesions. Only one out of these 4 studies, dealing with rheumatoid arthritis, evaluated more than 20 patients. Twelve other cross-sectional or prospective longitudinal studies compared eMRI versus another gold standard (arthroscopy, surgery...); sample sizes were generally small. The heterogeneity of the primary study parameters (population; equipment, technical parameters and study comparator; evaluated outcomes) and the presence of several methodological limitations prohibit firm overall conclusions.

Many of the other studies included in the AHRQ report 2011 were case-control evaluations in which controls were mostly healthy subjects; or studies evaluating different imaging sequences of one type of eMRI, evaluating anatomic measurements, comparing 2 different eMRI devices, etc.

5.3.2 HAS report 2012

The HAS report published in 2012 performed an extensive literature search in several databases including evidence from 1/2007 to 2/2012, and was meant to update and replace the previous HAS report (2008).³ It discussed the diagnostic use of ≤ 1 Tesla MRI equipments for osteo-articular evaluation of the extremities. This could be eMRI devices, or whole body open MRI devices with a field strength of ≤ 1 Tesla. The search strategy in this report was not restricted to low-field strength and also included high-field MRI. Based on the AMSTAR checklist rating, the HAS report 2012 was labelled as a high quality review (see also Appendix 1.2).

This report mainly concentrated on publications directly comparing the diagnostic efficacy, or clinical effect on patient outcomes, of ≤ 1 Tesla MRI systems versus high-field MRI systems; or comparing ≤ 1 Tesla MRI systems versus another valid diagnostic “gold standard” for the pathology under evaluation. Only studies of sufficient methodological quality and describing clinically relevant parameters were included.

No study could be included dealing with the clinical effect on patient outcomes; 6 studies were included dealing with diagnostic efficacy. Three of these 6 studies (n=75) directly compared ≤ 1 Tesla versus high-field MRI devices; 3 studies (n=182) compared ≤ 1 Tesla MRI devices versus another “gold standard”. Five studies concerned rheumatoid arthritis; one study evaluated arthrosis of the knee. The authors of the HAS report 2012 discussed the limited number of studies that could be included, and the small number of patients in these studies. They also discussed the many methodological flaws, such as lack of representativeness of the included study population for the true diagnostic population, utilisation of outcomes with poor clinical relevance (e.g. in the gonarthrosis study), and poor reporting of some technical parameters. The diagnostic parameters evaluated are not accuracy, sensitivity or specificity, but only diagnostic concordance between the index test and the comparator (high-field MRI devices or “gold standard”). Therefore the authors concluded that they could not draw firm conclusions regarding the diagnostic accuracy or clinical added value of ≤ 1 Tesla MRI systems in osteo-articular evaluations of the limbs.



5.4 Conclusion

All primary studies included in the two reviews aimed at evaluating the diagnostic accuracy of ≤ 1 Tesla MRI devices, or their clinical effect on patient outcomes. The retrieved publications, limited in number, mainly dealt with three population subgroups:

- rheumatoid arthritis,
- acute extremity injuries,
- degenerative joint lesions.

With the exception of 1 RCT, all these studies could be situated at level 1 or 2 of the diagnostic hierarchy of Fryback and Thornbury, evaluating technical quality and/or diagnostic properties (accuracy, sensitivity, and specificity) of low-field eMRI, against high-field MRI or against another gold standard.¹³ The presence of several methodological limitations and the heterogeneity of the study parameters prohibited firm overall conclusions, which implies that the diagnostic efficacy of low-field eMRI at Fryback and Thornbury level 1 and 2 has not sufficiently been proven yet.

The clinical condition most evaluated at level 1 or 2 was rheumatoid arthritis. The diagnostic efficacy of conventional high-field MRI has been well-established for several medical conditions involving the limbs, e.g. for several pathological conditions of the knee, but its value in the evaluation of rheumatoid arthritis has not yet been fully established.¹⁹⁻²¹ Moreover, if MRI would be able to detect progression of rheumatoid arthritis at an earlier stage than other diagnostic tests (e.g. blood markers, X-ray, ultrasound), it remains to be established whether medical treatment at this early stage and based on the MRI results, would provide additional benefits for the patient.^{20, 21}

In the two reviews, only one RCT was included that evaluated the impact of eMRI on diagnostic thinking, patient management plan, patient outcomes, or societal costs (level 3 to 6 of the diagnostic hierarchy of Fryback and Thornbury). The study evaluated acute wrist, knee and ankle trauma. At level 3 of the diagnostic hierarchy of Fryback and Thornbury, eMR imaging produced some change in the referring physician's diagnostic thinking as compared with plain radiography. For all three types of acute injuries, it allowed for better prediction of treatment need, but not of patients who could be discharged without further follow-up. At the levels 4 to 6 of the diagnostic hierarchy model, eMR imaging yielded no advantages in patients with acute wrist or ankle injuries as compared with plain radiography. In patients with knee injuries some advantages were noticed (reduction of additional diagnostic procedures, improved quality of life). Given the main research question for the present report, whether eMRI could take over extremity evaluations currently performed on whole body MRI scanners, a weakness of this RCT is that it did not include a comparison to conventional high-field whole body MRI.

The reviews discussed above did not find primary studies on the diagnostic properties of high-field eMRI, and the additional search for primary studies (2012-2013) did not yield such studies either. It can be assumed that high-field eMRI devices have the same diagnostic efficacy for disease conditions of the extremities as compared to high-field whole body MRI, if they are fitted with comparable peripheral equipment (gradient system, RF coil system, computer program...) and if the field-of-view of the eMRI device is sufficient for the diagnostic indications that will be dealt with.



A limitation of the present literature review is that only 2 databases (Medline- Cochrane Database of systematic reviews) have been included, and that only a limited search strategy has been applied. Terms specific to eMRI were included in the search strategy. As a result, it is possible that relevant information on MRI without specific reference to eMRI was not identified. On the other hand, extending the search strategy with general MRI terms would result in a huge amount of irrelevant references. Due to time considerations, the current search terms were preferred to provide an optimal balance of sensitivity and specificity of the search strategy.

In summary, the diagnostic efficacy of low-field eMRI against high-field MRI or against another gold standard for disease conditions of the extremities has not sufficiently been proven yet at level 1 and 2 of the hierarchical model of diagnostic efficacy of Fryback and Thornbury (1991).¹³ Since demonstration of efficacy at each lower level in this hierarchy is necessary, but not sufficient, to assure efficacy at higher levels, efficacy at higher levels is essential but remains to be demonstrated. For high-field eMRI devices, it can be assumed that they have the same diagnostic efficacy as compared to high-field whole body MRI, if they are fitted with comparable peripheral equipment (gradient system, RF coil system, computer program...). However, the bore configuration and the maximal field of view of the high-field eMRI might limit the number of extremity disease conditions for which the eMRI can be used. The US and the Netherlands have already considerable experience with eMRI. In Belgium, however, to our knowledge, no high-field eMRI are currently in routine use. According to the consulted Belgian experts (see colophon), the algorithms deserve further optimization. Depending on the evolution of these devices in the future, it might be necessary to reconsider their use for disease conditions of the extremities as a substitution for high-field whole body MRI.

6 THE CONTEXT OF MEDICAL IMAGING IN BELGIUM: RECENT INITIATIVES

6.1 IMA report

The Intermutualistic Agency (IMA) published a report (2009) on medical imaging in Belgium based on data from the “permanent sample” covering the period 2002 to 2008.²² The “permanent sample” is a weighted sample taken from the longitudinal data of the compulsory Belgian national health insurance, gathered and provided by the sickness funds. There was an increasing use of all types of medical imaging. For dental imaging the overall number of images slightly decreased, but there was a clear shift towards panoramic images. Over the period 2002-2008, there was a strong upward trend for CT (from about 19 000 to 39 000, or +12.7% yearly), interventional therapeutic imaging (from 3800 to 9100, +15.4% yearly), and MRI (from 7000 to 11 900, or +9.4% yearly). The trend was also positive for both ultrasound (from 91 000 to 125 000, or +5.5% yearly) and X-ray (from 166 000 to 191 000, or +2.4% yearly).

Further, the IMA report pointed to some other elements that might ask for attention:

- According to the IMA, the knowledge of the radiation risk and of the guidelines for medical imaging can improve among prescribers.²²
- The IMA report mentions that for many indications, MRI should be seen as a non-ionizing alternative for CT. In fact, according to the guidelines, MRI is even superior to CT for several indications. The authors of the IMA report mentioned that the cost of infrastructure for CT and MRI is becoming more similar. Nevertheless, many hospitals opt to purchase additional CT devices. This might be due to the total number of MRI devices being limited (programmed) per hospital by the federal government. In addition, the current financing of providers of imaging activities might be more favorable for CT compared to MRI.²²



6.2 Report College of Radiology

In 2012, the Belgian College of Radiology published the results of a prospective multicentre study on the use of the recommendations for medical imaging in Belgium.¹ This study aimed at exploring the correlation between the clinical pathology presented by the patient, and the medical imaging examinations prescribed by the physicians referring their patient. The study looked for patterns that could explain the continuous increase in the use of medical imaging. It was also checked whether the prescriptions were in line with the existing Belgian recommendations on medical imaging. These recommendations have been developed by the Belgian Consilium Radiologicum and are available online^a.

Furthermore, the study investigate whether it would be possible to stop the increase in radiation exposure due to X-rays and CT examinations in Belgium, without compromising the availability of imaging where appropriate as well as the quality of the diagnostic information obtained.

Indeed, in 2006 the Belgian Superior Health Council (Hoge Gezondheidsraad/ Conseil Supérieur de la Santé) reported that the X-ray exposure based on medical imaging in Belgium was about half of the overall exposure and 4 to 5 times higher compared with the Netherlands and the UK.^b This report also showed that the level of ionising radiation exposure of CT varies considerably with the type of CT equipment and the examined body part.

The study of the Belgian College of Radiology was performed between January 2011 and February 2012. Seven centres participated: the university centres CHU de Charleroi (Charleroi & Montigny-le-Tilleul), Erasme/ULB (Anderlecht), UZ Leuven (Leuven), and UZ Gent (Gent); and the general hospitals Saint-Luc (Bouge), AZ Sint-Jan (Brugge), AZ Groeninge (Kortrijk). Both ambulatory and hospitalized patients could

participate if they were referred by their physician for medical imaging for one of the following pathologies: low back pain, rheumatoid arthritis and spondyloarthropathy, rhinosinusitis, colon cancer, and acute abdominal pathology.¹ The study included 792 referrals. A researcher, blinded for the clinical information provided by the referring physician, gained information from the participating patients by taking the medical history, and also performed a clinical exam. The researcher, also blinded for the medical imaging examination(s) prescribed by the referring physician, then listed the necessary imaging examination(s) (X-ray, MRI, CT, ultrasound) taking into account the Belgian medical imaging recommendations. The imaging examination(s) prescribed by the referring physician were then compared to the imaging examination(s) listed by the researcher, thereby focusing on X-ray, CT and MRI.

This comparison led to interesting findings: based on the study sample and the selected pathologies, there could be a reduction of 25.8% for the number of X-rays and 42.8% for the number of CTs when the available guidelines would be applied. The authors mentioned that this reduction of X-rays and CT examinations would be offset by an increase of 15.1% in number of MRIs. The changes in absolute numbers by applying the guidelines showed a much larger decrease in the number of X-rays (-108) and CT (-203) versus a much smaller increase in MRI (+27). The largest reduction in both relative and absolute numbers would be for the number of CT examinations of the lumbar spine: -81.6% (-151); at the same time MRI of the lumbar spine would increase by 12%. The large reduction in the number of CT scans and X-rays could entail a large potential drop in both radiation and financial burden. For more details, the interested reader is referred to the original report.¹

Besides the prospective multicentre study, the report discussed also the results of a small evaluation of the knowledge of medical imaging recommendations and radioprotection, performed among 47 medical assistants training to become a medical specialist. Included were trainees in orthopedics (1/8th of the sample), radiology (1/8th), surgery (1/4th), internal medicine (1/4th) and other specialties (neurology, ophtalmology, psychiatry, ENT (ear-nose-throat)) (1/4th). The best results were obtained by the trainees in radiology and the trainees in orthopedics.

^a www.health.belgium.be/richtlijnen-medische-beeldvorming;
www.health.belgium.be/recommandations-imagerie-medicale

^b http://health.belgium.be/internet2Prd/groups/public/@public/@shc/document/s/ie2divers/10820441_nl.pdf;
http://www.health.belgium.be/internet2Prd/groups/public/@public/@shc/documents/ie2divers/10820441_fr.pdf



Overall, it can be concluded based on the report of the College of Radiology:

- By applying good clinical practice recommendations for medical imaging, it is possible to reduce CT examinations, which are known to be associated with a very high radiation exposure. This would imply an increase of MRI examinations.
- A better adherence to the medical imaging recommendations would immediately lead to an increase in imaging quality, a decrease of radiation exposure and less RIZIV-INAMI expenditures for imaging.
- The problem of the waiting lists for MRI examinations may not be completely solved when imaging prescriptions are more in agreement with the guidance. There is currently a limitation of the number of MRI systems allowed in Belgium. In addition to a better application of the recommendations for imaging prescription, a slight increase of the number of MRI systems in Belgium should be considered.
- The existing Belgian guidelines need to be updated regularly and to be completed for domains not yet included or still under debate, as became clear during the study.
- Referring physicians should have a thorough knowledge of the medical imaging recommendations, and further initiatives to support this are necessary.
- Radiologists might play a more important role in the prescription of medical imaging and in determining the appropriate medical imaging examinations for the referred patients. This gatekeeper role and systems of stepwise imaging is to be developed further.

For the full list of recommendations, we refer to the original report.¹ In our discussion we reflect further on these important findings.

6.3 Recent policy initiatives in medical imaging

In October 2010, the National Institute for Health and Disability Insurance RIZIV/INAMI in collaboration with the Federal Public Service (FPS) Health, Food Chain Safety and Environment, has launched an awareness campaign for prescribers (http://www.riziv.be/care/nl/doctors/promotion-quality/medical_imagery/).

The campaign is addressed to physicians to make them aware of the guidelines and thus steer their prescribing behaviour. The brochure focused on a selection of examinations with very limited indications. It was estimated that a better adherence to the guidelines could reduce the exposure to ionizing radiation by imaging tests by at least 25% and save €30 million annually. Together with the FANC (Federal Agency for Nuclear Control) and the FPS Health, Food Chain Safety and Environment, this campaign was complemented by other actions to sensitize both the prescribers, providers and the population.

In 2009, BELMIP (Belgian Medical Imaging Platform), formerly known as 'Commission Marchal', was established. The goal of this platform is to publish guidelines (<http://www.health.belgium.be/richtlijnen-medische-beeldvorming>), to raise the awareness of doctors and patients (<http://www.zuinigmetstraling.be>) and to introduce a quality system to keep the quality of medical imaging at a high level.²³

In March 2013, a report has been published by the National council for hospital facilities (Nationale Raad voor Ziekenhuisvoorzieningen/Conseil national des Etablissements hospitaliers).²³ This report deals with the reduction of ionizing radiation and a better use of the guidelines, setting up a registry of medical imaging equipment in use in Belgium, advising on the number of medical imaging devices that should be installed, etc.. For a detailed overview of their advice, we refer to the original reference.²³



From 1 March 2013 on, request forms for medical imaging are standardized and must contain the following elements^{24, 25}:

- the diagnostic questioning
- the necessary clinical elements in order to clarify the clinical context for the radiologist
- other important elements such as potential pregnancy, allergy, diabetes, renal failure, medical devices,...
- the proposed medical imaging examination
- only one request per diagnostic question is allowed.

The primary aim of these standardized forms was to enhance communication between the prescriber and the radiologist in order to set the right type of medical imaging to the respective case.

7 DISCUSSION

7.1 Belgian situation

Over the last years it has become clear that the X-ray exposure based on medical imaging in Belgium is about half of the overall exposure and 4 to 5 times higher compared with the Netherlands and the UK (Hoge Gezondheidsraad/ Conseil Supérieur de la Santé, 2006)^b. There is a huge problem of inappropriate prescription of such imaging in hospitals and in ambulatory care. This X-ray exposure leads to an increase of cancer incidence that can be avoided. Campaigns by government (RIZIV/INAMI) try to obtain a better adherence of prescribers to the guidelines for imaging. Guidelines for imaging list many indications for which MRI has been shown to be the more informative and appropriate imaging modality. MRI is not based on X-rays and is accepted not to be carcinogenic. However, safety limitations apply for materials sensitive to the strong magnetic field. Unfortunately, in contrast to RX and CT, MRI systems are not yet available in every hospital in Belgium, limiting the accessibility. In addition, patient throughput of an MRI system may be limited, certainly when high quality imaging is aimed for in complex indications. Waiting lists therefore tend to become very long.

Given the waiting list problem, CT scan may be used instead of MRI. In particular, CT-arthrography (with contrast injection) may be used instead of MRI, increasing ionising radiation exposure, iodine contrast risk and increasing use of risky invasive procedures (contrast injection).

7.2 Is eMRI the solution

Before deciding to install new MRI systems to improve accessibility and to reduce waiting lists, it was requested to KCE to evaluate the possible role of eMRI, a less expensive MRI system with a limited but not well-defined set of extremity-only indications. The literature review in the present report demonstrated that evidence to support or refute the use of low-field eMRI is lacking; and experts question the quality of this imaging technique. In theory, quality of images produced using high-field ($\geq 1.5T$) eMRI can be as good as those obtained using a regular MRI system with a similar magnetic field strength combined with similar peripheral equipment (gradient system...); however the bore configuration and the maximal field



of view of the high-field eMRI might limit the number of disease conditions of the extremities for which the eMRI can be used.

According to the Belgian experts consulted, in most hospitals the number of patients with evidence (expert opinion)-based indications for high-field eMRI may not justify the purchase of a dedicated MRI system. Experts also stated that these patients are often “filling the gaps” in the waiting list of regular MRIs. Therefore, according to this expert opinion, it cannot be expected that the introduction of an eMRI system will have any significant impact on the waiting list problem. However, this expert opinion may be centre-specific. Furthermore, no data are available on the volume of eMRI indications to support or contradict this statement.

If there is a place for high-field eMRI systems, this would be in very high volume centres that have sufficient (evidence-based) imaging requests that can be performed with eMRI, while the capacity of the regular MRI systems is already efficiently used. Depending on the evolution of these devices in the future, it might be necessary to reconsider their use for disease conditions of the extremities as a substitution for high-field whole body MRI.

7.3 What are the needs

There is not much information available to calculate the required number and type of imaging equipments on a scientific basis. Last year, the Belgian College of Radiology published an important report including the results of a well-performed study gathering information on the appropriateness of medical imaging requests in seven Belgian hospitals. In the study sample and for the medical indications included, there was a large potential for reduction of the number of radiographs (-25.8%) and CTs (-42.8%), while the number of justified MRI would increase (+15.1%) if the Belgian imaging recommendations would have been applied. The difference in absolute numbers was even more remarkable. The authors mentioned the two causes of excessive CT use: wrong indication and the waiting lists for MRI.

Extrapolation of the study results to calculate the needs for additional MRI in Belgium should take into account a possible effect of the selection bias. The seven selected centres, including several large referral centres, are probably not fully representative for the Belgian situation. There might be a difference in the mix of medical conditions dealt with in these hospitals, as compared to smaller hospitals. Also, it could be speculated that the knowledge of and adherence to imaging guidelines is better in such large teaching hospitals compared with the other hospitals, especially for more complex indications. The study did also not include all indications for which there are imaging requests. Furthermore, with respect to eMRI, none of the diseases studied truly reflect the patient population for which eMRI would be applicable. As a result, it does not allow us to make a more precise calculation of the number of needed (e)MRIs and CTs in Belgium. On the other hand, since 1 March 2013, request forms for medical imaging are standardized and mention, among others, the following elements: the diagnostic questioning, the necessary clinical elements in order to clarify the clinical context for the radiologist, and the proposed medical imaging examination. In the future, this information if completed correctly and analyzed, could provide more insight in the needed volume of CT, MRI and other imaging equipment.

7.4 Request behaviour

The study of the Belgian College of Radiology concluded, among others, that not the radiologists are responsible for the increase in the number of executed imaging examinations, but the requesting physicians.¹ It is also concluded that the referring physician must know the recommendations and apply them.¹ The radiologist is however the best placed expert to know the (evolution in) imaging recommendations, and could act as a gatekeeper.¹ Experts stated in a recent advice report on medical imaging that the radiologist should at least have a right for substitution. Ideally, this should even be a substitution obligation.²³

If the gatekeeper role of the radiologist is implemented, it should be provided in a financing context which does not induce extra imaging. This conflict of interest situation is typical for a fee for service system as is still applicable in most hospitals in Belgium.



Good practice guidelines for the use of medical imaging have been elaborated by the Collegium Radiologicum (cfr. supra). For many indications, the most appropriate modality of imaging has been defined. It could be considered that the prescriber needs to mention the rationale in case of a clear deviation from the guidelines. Electronic prescriptions using intelligent software could provide an efficient solution.¹ The use of such electronic prescription system could become a condition for performing the imaging and for its reimbursement, when proven successful after a pilot evaluation period. Of equal importance may be the organization of educational sessions for prescribers on the imaging guidelines with obligatory participation as part of the continuing medical education.

7.5 Further steps

7.5.1 Reinvestments

The study of the Belgian College of Radiology points to an overuse of CT scans, also for indications where MRI would be more appropriate. Also prescriptions for MRI are not always evidence based. An exact estimate of the required capacity for CT, MRI and other imaging techniques is not possible. Yet, it is clear that the supply side needs to shift towards more MRI and less CT scans.

Hospitals with an overcapacity of CT and a sufficient MRI capacity should not replace all depreciated CT equipment. Hospitals with a sufficient capacity of CT and an undercapacity of MRI should be able to invest in MRI without sacrificing their CT capacity. Arrangements should be made in every hospital such that access to MRI is guaranteed, also for urgent cases.

This reinvestment from CT to MRI does not mean that in the long term a higher overall budget for imaging is needed. The research of the Belgian College of Radiology shows that in absolute numbers the CT overcapacity is probably much higher than the undercapacity of MRI. In the coming years, extra MRI investments may lead to higher budgetary needs. However, if CT overcapacity is reduced and inappropriate imaging requests are avoided or blocked, the budgetary impact should be reduced significantly.

7.5.2 Supporting financing system

The financing system should stimulate evidence-based imaging request behaviour, assure high-quality imaging and avoid unnecessary X-ray exposure. Today, in contrast with MRI, CT scanners do not benefit from A3 and B3 financing (fixed yearly lump sum to the hospital for the investment and operational costs, except physician related costs). The only financing source for CT scanners is the NIDHI fee for service. Yet, it has been suggested that the CT-scan fee for service financing is sufficient to turn each additional CT system into a profit centre for the hospital.²² This cannot be said of each additional MRI system as there are legal restrictions on the number of systems that can benefit from the A3/B3 financing. Furthermore, if high-quality MRI is performed in complex indications, the throughput of patients per day is lower.

Given that the current fee for service system does not require a minimum MRI quality level, centres might feel induced to opt for lower quality MRI scans that take less time to perform. This way they may cope better with the long waiting lists and even turn the MRI system into a hospital profit centre. The current financing situation therefore favors more CT scans, and lower quality MRI, the opposite of what is preferred from a patient management and population safety perspective.



8 CONCLUSION

In contrast to RX and CT, the spread of MRI systems is strictly regulated in Belgium. MRI is not yet available in every hospital in Belgium, limiting the accessibility. In addition, there is an important problem with the prescriptions of imaging: sometimes imaging is not necessary or the best technique is not prescribed. Often a CT is prescribed instead of MRI, leading to an overall high X-ray exposure in Belgium as compared to other countries. This may also be related to the much longer waiting lists for MRI compared with CT.

Campaigns by government (RIZIV/INAMI) have started to create awareness for the problem of inappropriate prescription of CT, also pointing to the induction of cancer by X-ray exposure. The campaigns may need to be repeated and strengthened, e.g. using the system of continuing medical education.

A better adherence to the imaging guidelines should lower the volume of imaging in general and lead to a (small) increase in the number of MRI systems and relative shift from CT to MRI. A better adherence to the medical imaging recommendations would also immediately lead to an increase in imaging quality, a decrease of radiation exposure and less RIZIV-INAMI expenditures for imaging.

Before deciding to install new MRI systems to improve accessibility and reduce the MRI waiting lists, it was requested to KCE whether there was any role for eMRI, a less expensive MRI system with a limited set of extremity-only indications. We did not identify a medical need for eMRI in addition to the regular MRI systems. According the experts consulted, in most hospitals the number of patients with evidence(expert opinion)-based indications for high-field ($\geq 1.5T$) eMRI may not justify the purchase of a dedicated MRI system. Often, patients requiring MRI of the extremities are currently “filling the gaps” in the waiting list of regular MRIs. Therefore, according to expert opinion, it cannot be expected that the introduction of an eMRI system will have any significant impact on the waiting list problem. Further information on the volume per indication, and thus the potential of (high-field) eMRI, is necessary to support or contradict this statement.

The financing system should stimulate evidence-based imaging request behaviour, assure high-quality imaging and avoid unnecessary X-ray exposure. The current financing situation rather favors more CT scans, and sometimes lower quality MRI, the opposite of what is preferred from a patient management and population safety perspective. Adapting the financial stimuli may thus be necessary. The financing system should also guarantee that a gatekeeper role of the radiologist can be realised without any risk of inducing extra imaging, a conflict of interest situation that is typical for a fee for service system as is still applicable in most hospitals in Belgium.



■ APPENDICES

APPENDIX 1. APPENDIX TO CHAPTER 5

Appendix 1.1. Search strategy and literature selection

Appendix 1.1.1. Systematic reviews from Databases

Database: Medline (PubMed)

Date of search: August 2012; update 10 July 2013

Selection criteria:

- English, French, Dutch or German review;
- based on a systematic literature search and searched databases are mentioned;
- including randomized controlled trials (RCTs) or prospective diagnostic accuracy studies using a gold standard;
- having performed a quality appraisal of the included studies and/or including data extraction tables;
- corresponding to the in-/exclusioncriteria related to the research question.

Search strategies:

1.

("Magnetic Resonance Imaging"[Mesh]) AND (extremity OR extremities) AND dedicated

Filters: review

results: 15; none relevant

2.

("Magnetic Resonance Imaging"[Mesh]) AND ("extremity only" OR extremity-only)

Filters: Review

results: 0

3.

("Magnetic Resonance Imaging"[Mesh]) AND ("low field" OR low-field)

Filters: Review

results: 51; none relevant

4.



("Magnetic Resonance Imaging"[Mesh]) AND ("mid field" OR mid-field)

Filters: Review

results: 3; none relevant

Database: Cochrane Database of systematic reviews

Date of search: August 2012; update 10 July 2013

Selection criteria:

-English, French, Dutch or German;

-corresponding to in-/exclusioncriteria for the research question

Search strategies:

magnetic resonance imaging:ti,ab,kw

results: 24 cochrane reviews: none relevant

MRI and extremity

results: 57 cochrane reviews, 4 other reviews: none relevant (MRI and extremities: idem)

MRI and dedicated

results: 21 cochrane reviews, 3 other reviews: none relevant

[Appendix 1.1.2. Guideline Websites](#)

Date of search: August 2012; update 10 July 2013

Selection criteria:

-English, French, Dutch or German review;

-based on a systematic literature search and searched databases are mentioned;

-including randomized controlled trials (RCTs) or prospective diagnostic accuracy studies using a gold standard;

-having performed a quality appraisal of the included studies and/or including data extraction tables;

-corresponding to the in-/exclusioncriteria related to the research question.

Search strategies:

"MRI"; "IRM"; combinations of "MRI", "extremity", "extremities", "dedicated".



Table – Guideline websites.

	Website	# relevant	In/excluded
Guidelines International Network (GIN)	http://www.g-i-n.net/	0 relevant	---
National Guideline Clearinghouse	http://www.guideline.gov/	0 relevant	---
Centre for reviews and dissemination: CRD Database (DARE, NHS EED and HTA Database)	http://www.crd.york.ac.uk/crdweb/	Dedicated MRI in osteoarticular. Comite d'Evaluation et de Diffusion des Innovations Technologiques CEDIT (2007) ⁴	excluded: searched databases not mentioned; no quality appraisal of the included studies and no data extraction tables
Tripdatabase	www.tripdatabase.com	Horizon Scanning Technology Prioritising Summary. 0.2-0.5 Tesla MRI for the detection of arthritis and musculoskeletal disease. Australia and New Zealand Horizon Scanning Network (2009) ²⁶	excluded: searched databases not mentioned
		Horizon Scanning Technology Prioritising Summary. MRI for the diagnosis of rheumatoid arthritis. Australia and New Zealand Horizon Scanning Network (2009) ²⁷	excluded: searched databases not mentioned
Euroscan	http://euroscan.org.uk/	Issues in emerging health technologies. Open Magnetic Resonance Imaging (MRI) Scanners. Canadian Agency for Drugs and Technologies in Health CADTH (2006) ²⁸	excluded: searched databases not mentioned; no quality appraisal of the included studies and no data extraction tables
Haute Autorité de Santé (HAS)	http://bfes.has-sante.fr/HTML/indexBFES_HAS.html	Exploration ostéo-articulaire des membres par IRM : intérêt diagnostique des équipements à champ modéré et des équipements dédiés - Rapport d'évaluation (2012) ³	included
Agency for Healthcare Research &	http://www.ahrq.gov/	Technical Brief: Emerging MRI Technologies for Imaging	included



Quality (AHRQ)	Musculoskeletal Disorders Under Loading Stress. (2011) ²
National Institute for Health and Care Excellence (NICE) www.nice.org.uk/	0 relevant ---

Appendix 1.1.3. Search for RCTs

Database: Medline (PubMed)

Date of search: 27 August 2013

Selection criteria:

- English, French, Dutch or German;
- randomized controlled trials;
- RCTs directly comparing diagnostic efficacy between eMRI and conventional high-field (≥1.5T) whole body MRI. RCTs evaluating the diagnostic properties of high-field eMRI (≥1.5T) were accepted even if no direct comparison to conventional high-field whole body MRI was made.
- corresponding to in-/exclusioncriteria for the research question

Search strategies:

1. 34 results, none retained

Search	Query	Items found
#1	"Magnetic Resonance Imaging"[Mesh]	286761
#2	("extremities"[MeSH Terms] OR extremity[Text Word])	276668
#3	(#1) AND #2	10355
#4	(#1) AND #2 Filters: Randomized Controlled Trial; Clinical Trial; Publication date from 2012/01/01 to 2013/12/31	34

2. 2 results, none retained

Search	Query	Items found
#1	"Magnetic Resonance Imaging"[Mesh]	286761
#2	(#1) AND ("low-field" OR low-field)	774
#3	(#1) AND ("low-field" OR low-field) Filters: Clinical Trial; Randomized Controlled Trial; Publication date from 2012/01/01 to 2013/12/31	2



3. 0 results

Search	Query	Items found
#1	"Magnetic Resonance Imaging"[Mesh]	286761
#2	(#1) AND ("mid field" OR mid-field)	37
#3	(#1) AND ("mid field" OR mid-field) Filters: Clinical Trial; Randomized Controlled Trial; Publication date from 2012/01/01 to 2013/12/31	0

4. 7 results, none retained

Search	Query	Items found
#1	"Magnetic Resonance Imaging"[Mesh]	286761
#2	(#1) AND dedicated	1400
#3	(#1) AND dedicated Filters: Clinical Trial; Randomized Controlled Trial; Publication date from 2012/01/01 to 2013/12/31	7

Appendix 1.2. Quality Appraisal

AMSTAR checklist of included systematic reviews

	A priori study design	Duplicate study selection and data extraction	Comprehensive literature search	Publication status not used as inclusion	List of in- and excluded studies	Characteristics of included studies provided	Study quality assessed and documented	Quality assessment used in conclusion	Appropriate methods to combine findings	Likelihood of publication bias assessed	Conflict of interest stated
	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11
AHRQ report 2011 ⁽²⁾	can't answer	yes	no (single database)	yes	no	yes	no	not applicable (no conclusions formulated)	not applicable (no pooling)	no	no
HAS report 2012 ⁽³⁾	yes	yes	yes	yes	yes	yes	yes	yes	not applicable (no pooling)	no	yes

Reference: http://amstar.ca/AMSTAR_Checklist.php



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