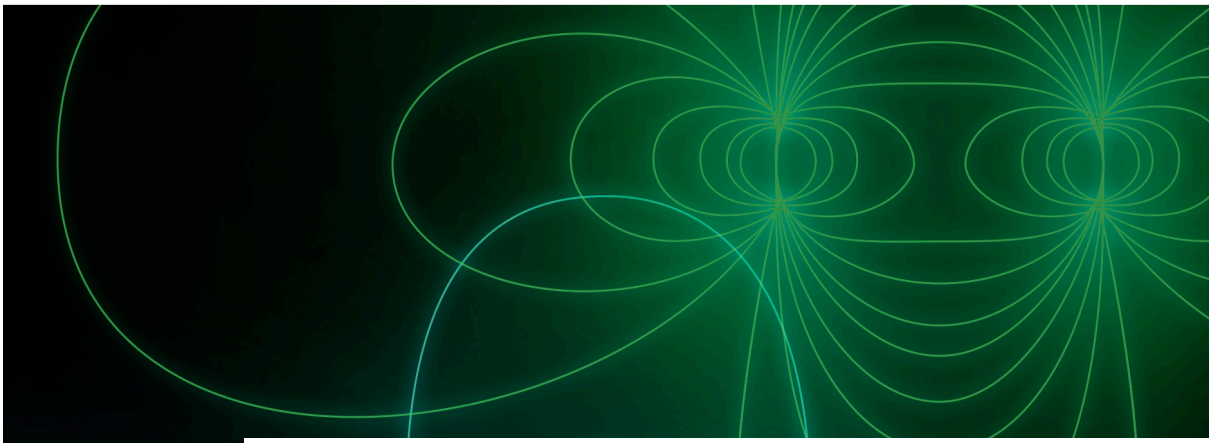
Safety and health effects in high and ultra-high field MR

Hansson, Boel

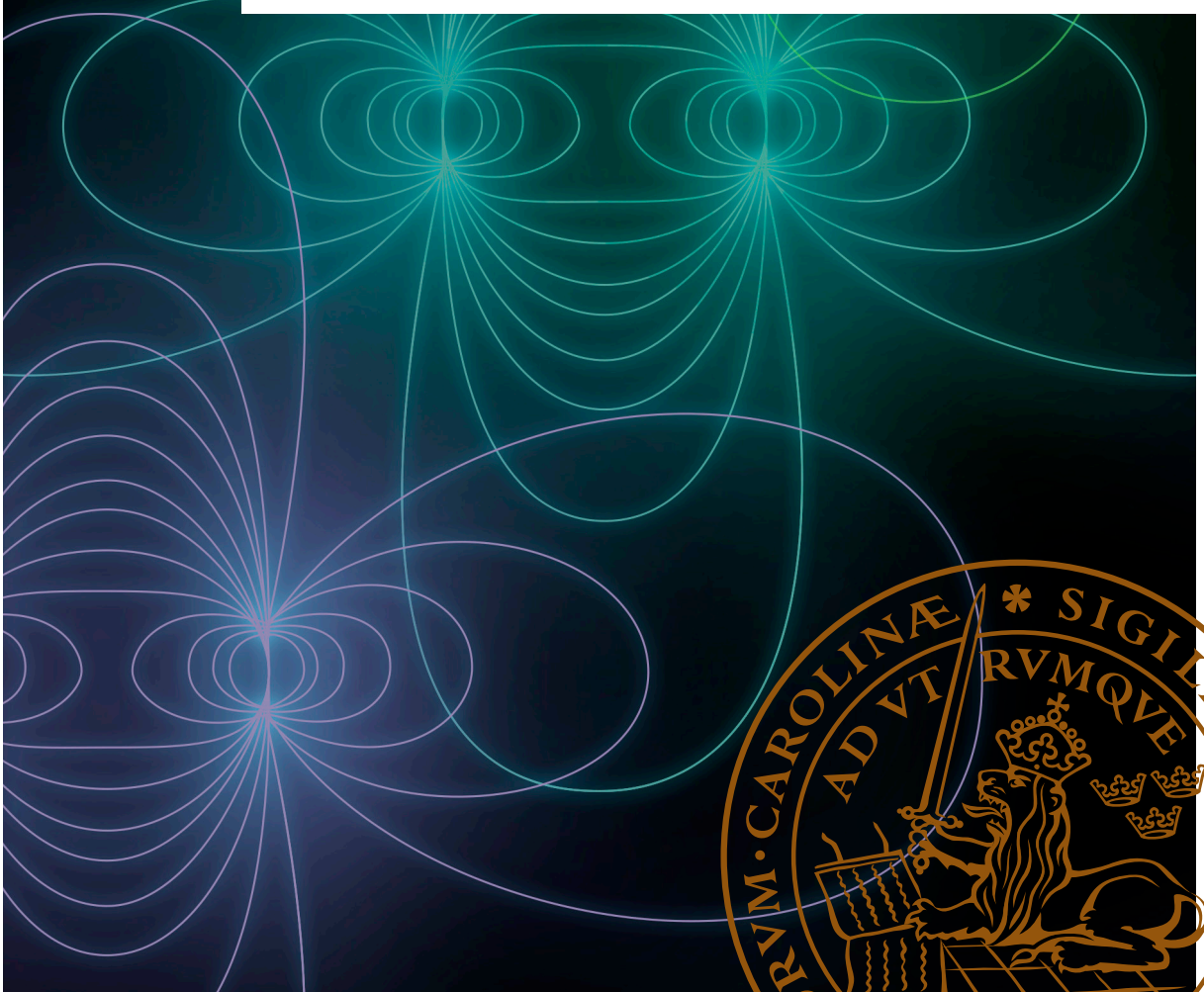
2020

Document Version:
Publisher's PDF, also known as Version of record



Safety and health effects in high and ultra-high field MR

BOEL HANSSON
DEPARTMENT OF CLINICAL SCIENCES, LUND | LUND UNIVERSITY



Safety and health effects in high and ultra-high field MR

Safety and health effects in high and ultra-high field MR

Boel Hansson

LUND
UNIVERSITY

DOCTORAL DISSERTATION
by due permission of the Faculty of Medicine, Lund University, Sweden.
To be defended at Segerfalksalen, Biomedical Centre, Lund University
September 11th 2020 at 09:00.

Faculty opponent
Dr. Christina Malamateniou
Division of Midwifery and Radiology, City, University of London, UK

Organization LUND UNIVERSITY	Document name Doctoral dissertation
Department of clinical sciences Lund Faculty of Medicine	Date of issue 11th of September 2020
Author Boel Hansson	Sponsoring organization

Title and subtitle
Safety and health effects in high and ultra-high field MR

Abstract

Background: More than 70 million magnetic resonance (MR) examinations are produced every year. Patients and personnel are exposed to electromagnetic fields at levels that exceed those normally found in our surroundings or in industry. Three types of electromagnetic field exposure must be considered in regard to MR safety: the strong force of the static magnetic field, the time-varying gradient magnetic field present during scanning, and the radio frequency field from the transmit coil. Most clinical MR scanners operate at 1.5Tesla (T) or 3T, but the number of ultra-high field scanners (UHF; above 4T) has increased over the last 15 years. This development has led to imaging of higher quality and provides the possibility of new insights into the pathophysiology of disease. MR safety work is a continuous effort of improvement to ensure the safety and health of our patients, healthy volunteers and personnel.

Aim: The overall aim of this thesis was to analyse health effects of MR, including short-term effects of UHF MR, and MR safety issues from the perspective of patients, healthy volunteers, and personnel.

Method: In paper I and II the individuals undergoing an MR examination at the National 7T MR facility at Skåne University Hospital were asked to fill in a questionnaire regarding their experience of short-term effects and health effects after the examination. In paper III MR and/or computed tomography (CT; control group) users in Sweden were invited to answer a web-based safety questionnaire sent to their units. Reported MR safety incidents were analysed and a risk assessment was performed. Documented screening procedures of subjects scheduled for a 7T MR examination during a period of four years (2016-2019) were analysed in paper IV.

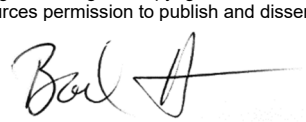
Results: Papers I and II showed that short-term effects representing physiological responses such as dizziness, inconsistent movement, nausea, headache, and metallic taste do occur in UHF, as well as individual psychological issues such as anxiety. Compared to the literature on older UHF systems, frequencies of short-term effects are higher in our studies. However, willingness to undergo future examinations was still high and suggestions for care improvement are given. In paper III results showed that safety incidents in clinical MR environments do occur and the risk levels of these incidents are high. MR personnel tended to have a false sense of security, as a high proportion of personnel members were sure that they would have been aware of any incident at their own department, while in reality, incidents had occurred without their knowledge. Paper IV showed benefits of a multi-step MR safety procedure with regard to detection of MR safety risks, at the same time as inadequacies in compliance with documentation routines were detected.

Conclusion: Health effects do occur in ultra-high field MR, but few subjects experience these effects as being so uncomfortable that they would lead to an aversion towards future examinations. Further, compliance and experience might be improved by focusing on pre-examination anxiety, communication, and supplying information before and during the examination. Safety incidents in clinical MR environments occur, have high potential risk levels and stay in contrast to a partly false sense of security among personnel. Although afflicted with inadequacies in compliance, a multi-step screening process offered benefits trough repetition and through the use of a documented structured screening interview and as result potential MR safety incidents are avoided.

Key words
Magnetic Resonance Imaging, UHF, MR safety, Patient compliance

Classification system and/or index terms (if any)

Supplementary bibliographical information		Language English
ISSN and key title 1652-8220 Safety and health effects in MR		ISBN 978-91-7619-947-3
Recipient's notes	Number of pages 83	Price
	Security classification	

Signature  Date 2020-07-30

Safety and health effects in high and ultra-high field MR

Boel Hansson

LUND
UNIVERSITY

Cover photo by Frida Nilsson Media-Tryck

Faculty of Medicine
Department of clinical sciences, Lund

ISBN 978-91-7619-947-3
ISSN 1652-8220

Printed in Sweden by Media-Tryck, Lund University
Lund 2020

I rörelse

Den mätta dagen, den är aldrig störst.
Den bästa dagen är den av törst.

Nog finns det mål och mening i vår färd –
men det är vägen, som är mödan värd.

Det bästa målet är en nattlång rast,
där elden tänds och brödet bryts i hast.

På ställen, där man sover blott en gång,
blir sömnen trygg och drömmen full av sång.

Bryt upp, bryt upp! Den nya dagen gryr.
Oändligt är vårt stora äventyr.

Karin Boye

Table of Contents

Abstract

Background

More than 70 million magnetic resonance (MR) examinations are produced every year. Patients and personnel are exposed to electromagnetic fields at levels that exceed those normally found in our surroundings or in industry. Three types of electromagnetic field exposure must be considered in regard to MR safety: the strong force of the static magnetic field, the time-varying gradient magnetic field present during scanning, and the radio frequency field from the transmit coil. Most clinical MR scanners operate at 1.5Tesla (T) or 3T, but the number of ultra-high field scanners (UHF; above 4T) has increased over the last 15 years. This development has led to imaging of higher quality and provides the possibility of new insights into the pathophysiology of disease. MR safety work is a continuous effort of improvement to ensure the safety and health of our patients, healthy volunteers and personnel.

Aim

The overall aim of this thesis was to analyse health effects of MR, including short-term effects of UHF MR, and MR safety issues from the perspective of patients, healthy volunteers, and personnel.

Method

In paper I and II the individuals undergoing an MR examination at the National 7T MR facility at Skåne University Hospital were asked to fill in a questionnaire regarding their experience of short-term effects and health effects after the examination. In paper III MR and/or computed tomography (CT; control group) users in Sweden were invited to answer a web-based safety questionnaire sent to their units. Reported MR safety incidents were analysed and a risk assessment was performed. Documented screening procedures of subjects scheduled for a 7T MR examination during a period of four years (2016-2019) were analysed in paper IV.

Results

Papers I and II showed that short-term effects representing physiological responses such as dizziness, inconsistent movement, nausea, headache, and metallic taste do occur in UHF, as well as individual psychological issues such as anxiety. Compared to the literature on older UHF systems, frequencies of short-term effects are higher in our studies. However, willingness to undergo future examinations was still high and suggestions for care improvement are given. In paper III results showed that safety incidents in clinical MR environments do occur and the risk levels of these incidents are high. MR personnel tended to have a false sense of security, as a high proportion of personnel members were sure that they would have been aware of any

incident at their own department, while in reality, incidents had occurred without their knowledge. Paper IV showed benefits of a multi-step MR safety procedure with regard to detection of MR safety risks, at the same time as inadequacies in compliance with documentation routines were detected.

Conclusion

Health effects do occur in ultra-high field MR, but few subjects experience these effects as being so uncomfortable that they would lead to an aversion towards future examinations. Further, compliance and experience might be improved by focusing on pre-examination anxiety, communication, and supplying information before and during the examination. Safety incidents in clinical MR environments occur, have high potential risk levels and stay in contrast to a partly false sense of security among personnel. Although afflicted with inadequacies in compliance, a multi-step screening process offered benefits trough repetition and through the use of a documented structured screening interview and as result potential MR safety incidents are avoided.

Original papers

The thesis for the doctoral degree is based on the following papers, which will be referred to in the text by their Roman numerals. The complete papers are appended at the end of the printed theses. Reprints were made with permission from the respective publishers.

I. Hansson B, Höglund P, Markenroth Bloch K, Nilsson M, Olsrud J, Wilén J, Björkman-Burtscher IM. Short-term effects experienced during examinations in an actively shielded 7 T MR. Bioelectromagnetics. 2019, May 40(4):234-249. PMID: 32196818

II. Hansson B, Markenroth Bloch K, Owman T, Nilsson M, Lätt J, Olsrud J, Björkman-Burtscher IM. Subjectively reported effects experienced in an actively shielded 7T MR – a large-scale study. J Magn Resonan Imaging. 2020, Mar 20:1-12. Online ahead of print. PMID: 32196818

III. Hansson B, Olsrud J, Wilén J, Owman T, Höglund P, Björkman-Burtscher IM. Swedish national survey on MR safety compared with CT: a false sense of security? Eur Radiol. 2020, 30(4):1918-1926. PMID: 32196818

IV. Hansson B, Simic M, Markenroth Bloch K, Owman T, Olsrud J, Sundgren PC, Björkman-Burtscher IM. Documented 7T MR safety screening interview in a multi-step safety screening process – an analysis of benefit and compliance in 1819 cases. Submitted 2020, June 10. European Radiology. Submission id: EURA-D-20-02538

Other scientific contributions

Scientific work by Boel Hansson related to but not included in this thesis.

Peer-reviewed original paper

Blankholm A and **Hansson B**, Incident reporting and level of MR safety education: A Danish national study. Radiography 2019 May;26(2):147-153. PMID: 32052744

Peer-reviewed conference abstracts

Spotorno N, Nilsson M, **Hansson B**, Andersson F, Leuzy A, van Westen D, Hansson O, Ronen I. Diffusion of NAA as a marker for tau pathology in Alzheimer's disease - a combined diffusion weighted MRS and positron emission tomography study. Abstract, ISMRM, e- congress due to pandemic, August 2020

Zampeli A, Björkman-Burtscher IM, Källén K, **Hansson B**, Markenroth Bloch K, Compagno Strandberg M. Morphological 7T MRI of malformations of cortical development in patients with focal epilepsy. Abstract, European Congress of epileptology, Annual meeting, Geneva, Italy, July 2020 (accepted, congress postponed due to pandemic)

Hansson B, Olsrud J, Wilén J, Owman T, Höglund P, Björkman-Burtscher IM. MR-safety in Sweden, poster and power pitch, ISMRM MR-safety workshop, Utrecht, The Netherlands, September 2019

Hansson B, Olsrud J, Wilén J, Owman T, Höglund P, Björkman-Burtscher IM. MR-säkerhet – en tickande bomb. Oral presentation. Röntgenveckan, Örebro, Sweden, September 2018

Hansson B, Källén K, Markenroth Bloch K, Nordqvist P, Helms G, Andersen M, Ståhlberg F, Sundgren P, Björkman-Burtscher IM. 7T-MR and epilepsy-patient compliance. Oral presentation, ESNR, Malmö, Sweden, September 2017

Hansson B, Olsrud J, Owman T, Frankel J, Wilén J, Höglund P & Björkman-Burtscher I. Swedish National survey on MR safety. Poster ISMRM/SMRT, Hawaii, April 2017

Hansson B. Short-term effects during examinations in an actively shielded 7T MR, oral presentation. ECR Vienna, Austria, March 2017

Hansson B, Olsrud J, Frankel J, Wilén J, Björkman-Burtscher IM. Swedish National survey on health effects on MR personnel – preliminary results. Poster ISMRM/SMRT Singapore, May 2106 (award: third place poster research)

Hansson B, Olsrud J, Nilsson M, Frankel J, Wilén J, Owman T, Arborelius J, Björkman-Burtscher IM. Short-term effects during examinations in an actively shielded 7T MR system. Poster ISMRM/SMRT, May 2016 Singapore.

Hansson B. National survey on health effects on MR personal. Röntgenveckan, Malmö, September 2015

Hansson B. 3 T Whole body scanner. Oral presentation, ECR, Vienna, Austria, March 2005

Non peer-reviewed scientific contributions

P Wallgårda, **B Hansson**. Incidenter vid MR-undersökningar vanligare än tidigare känt. Radio interview Sveriges Radio P4, Norrbotten and Dagens eko, March 2020

Hansson B, Olsrud J, Wilén J, Owman T, Höglund P, Björkman-Burtscher IM. MR-säkerhet – falsk trygghet. Oral presentation and panel discussion, National MR-safety workshop, Lund, Sweden, March 2020

Björkman-Burtscher IM, **Hansson B**. Från remiss till scan – vad kan gå fel och vem har ansvar. Oral presentation and panel discussion, National MR-safety workshop, Lund, Sweden, March 2020

Hansson B, Källén K, Markenroth Bloch K, Nordqvist P, Helms G, Andersen M, Ståhlberg F, Sundgren P, Björkman-Burtscher IM. 7T-MR and epilepsy-patient compliance. Oral presentation. Philips 7T User meeting, Nashville, US, September 2017

Hansson B. Short-term effects during examinations in an actively shielded 7T MR. ECR today, March 2017

Hansson B, Simic M, Owman T, Björkman-Burtscher I. MR-säkerhet en konstant utmaning som kräver kontinuerligt förbättringsarbete. Imago Medica, Nov 2017

Hansson B. Subjective experiences of 7T UHF. Oral presentation. Philips 7T User meeting, Örenäs Glumslöv, September 2015

Hansson B, Björkman-Burtscher I. Hälsoeffekter av starka magnetfält på personal verksam i kliniska magnetkameramiljöer – en enkätstudie. Röret – Svensk förening för röntgensjuksköterskor medlemstidskrift, nr 4, 2014

Abbreviations

ACR	American College of Radiology
AS	Actively Shielded
CT	Computed Tomography
fMRI	functional Magnetic Resonance Imaging
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
PNS	Peripheral Nerve Stimulation
PS	Passively Shielded
RF	Radio Frequency
SAR	Specific Absorption Rate
SF	Screening Form
UHF	Ultra-High Field
VAS	Visual Analogue Scale

Introduction

Magnetic resonance (MR) or MR imaging (MRI) involves an amazing combination of advanced science and engineering, and the scanners are often located in the radiology department of the hospital. It is an imaging method sensitive to the presence of water and its properties. The adult human body contains approximately 60% of water and the properties and amount of water in different tissues can alter dramatically as a result of disease or injury, which makes MR a very sensitive diagnostic tool. MR can image anatomy and pathology, but it can also be used to investigate organ function and to visualize metabolism (MR spectroscopy) and brain function (functional MRI) (1). The static magnetic field of a clinically used MR scanner today is 1.5 or 3Tesla (T). This magnetic field is approximately 30 000 to 60 000 times stronger than the earth's magnetic field at the surface, and roughly 300 to 600 times stronger than a refrigerator magnet (2). MR scanners today use superconductive magnets that require liquid helium to be used as a cryogenic cooling fluid. The magnetic field is always present (1) because an MR scanner is never turned off unless it is broken or discharged.

The versatility and flexibility of MR and its relatively safe and non-invasive nature, have led to a very large increase in demand for scans. Consequently, the number of installed MR scanners has increased over the last three decades (3), and more patients and personnel are exposed (4). The main motivation for the technological development of MR at ultra-high fields (UHF; above 4T) is the increased signal-to-noise-ratio (SNR) (5). This development has led to images of higher quality (6) and affords the possibility of obtaining new insights into the pathophysiology of disease (7) and the functionality of the human body (8). When UHF now translates into clinical use, it is important to investigate possible relationships between exposure to strong magnetic fields and health effects, and it may be necessary to revise routines related to patient preparation and handling of implants (4, 9). Although study subjects have been shown to tolerate ultra-high field strengths well, they have reported short-term effects such as dizziness, inconsistent movement, nausea, or metallic taste more frequently compared to high field MR (10-15). In general there is a positive attitude towards 7T MR examinations (12, 14, 15), and no serious adverse effects have been reported (4, 10, 16), but there might be room for improvements in terms of nursing care.

The general purpose of this thesis is to explore health effects related to MR, and MR safety issues from the perspective of patients, healthy volunteers, and personnel in high and ultra-high field MR, with the opportunity to generate results and recommendations that can be applied to a wide patient population and improve the working environment for health care personnel.

Background

Principle of MR

There are three types of electromagnetic field exposure in MR: 1 – the static magnetic field, generating a net magnetization vector in the human body; 2 – the gradient magnetic field, used to localize the MR signal in the three-dimensional body; and 3 – the radio-frequency field, energizing the magnetization vector and allowing conversion of tissue properties into MR images (17).

The MR signals that provide the information for the image are produced in the human tissue in response to radiofrequency (RF) pulses generated by a transmitter coil. The stronger the magnetic field, the higher the frequency. The signals produced in the body are subsequently detected by a receiver coil. To avoid RF from outside, which might interfere with the signals produced in the body, RF shielding is built into the magnet room in the form of a Faraday's cage, and it is important to keep the magnet room door closed during scanning (1). The intensity and duration of the RF pulse and the time of signal read out are some of the parameters defined by the pulse sequence. The intensity and duration of the pulse is described by the flip angle. A spin echo sequence is e.g. composed of a 90º pulse and a 180º pulse, followed by a read out of the signal, also called echo. Time to echo or echo time (TE) is the time between excitation – the 90º RF pulse – and the echo. In a spin echo sequence the 180º pulse is applied exactly halfway between the 90º pulse and the signal read out to form what is called a spin echo. Instead of using a 180º pulse to form the echo, it is possible to use magnetic field gradients, that is, spatially varying magnetic fields induced by the scanner, to create what is called a gradient echo. Sequences using this technique are called gradient echo sequences. A smaller excitation flip angle than 90º can then be used. Smaller flip angles and gradient echos are used to create images faster and to achieve different signal patterns (18).

The localization of the MR signals are achieved by short-term spatial variations in the magnetic field across the human body, called gradients. The gradients are produced by three sets of gradient coils, one for each orthogonal direction x, y or z. Through the gradient coils, large electrical currents rapidly switch on and off using controlled pulse sequences. The gradient coils are built into the magnet, and are responsible for the tapping, clicking, or loud beeping sound that can be heard when

undergoing an MR examination. The MR system is controlled via the operator's console in the control room (**Figure 1**), and this is where the pulse sequences are selected for each examination by the MR operator (1).

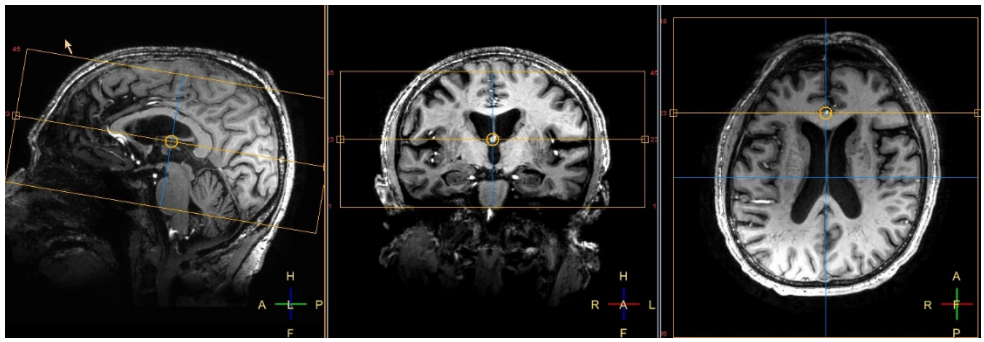


Figure 1.
MR operator's view when postioning the slices of the imaging sequence at the 7T MR scanner (Achieva; Philips, Best, the Netherlands) at the National 7T MR facility, Lund University and Skåne University Hospital

MR development

MR is a Nobel Prize winning technique. In 1952 Edward Purcell and Felix Bloch jointly received the Nobel Prize for their development of new methods for nuclear magnetic precision measurements and discoveries in connection to it. Nicolaas Bloembergen received the Nobel Prize in 1981 for his work in laser spectroscopy, and 10 years later, 1991, Richard Ernst received the Nobel Prize for his contribution to the development of the methodology of high resolution nuclear magnetic resonance spectroscopy. This was previous to the imaging era of MR. In 1973, Paul Lauterbur proposed using magnetic field gradients to distinguish between magnetic resonance signals originating from different locations combining this with a form of reconstruction from projections (already used in computed tomography (CT)). The use of gradients formed a base for MR and was recognised by the Nobel Committee in 2003. The same year, Sir Peter Mansfield was also recognised by the Nobel Committee for his contribution of selective excitation (1).

The technique subsequently developed rapidly through the 1980s, after Raymond Damadian and his colleagues built a superconducting magnet and produced the first human scan in 1977, and by 1996 there were 10 000 MR scanners installed worldwide (1). In 2015 there were more than 30 000 MR scanners producing over 70 million examinations per year. Although most of the MR scanners operate at 1.5T or 3T, the number of 7T scanners has increased over the last 15 years (19). The

development of ultra-high fields (UHF; above 4T) has led to images of higher quality (6) and affords the possibility of obtaining new insights into the pathophysiology of disease (7). Worldwide, approximately 30 passively shielded (PS) 7T MR scanners and 59 actively shielded (AS) 7T MR scanners have been installed (information obtained from the manufacturers; personal communication 2020). The development of AS scanners has been essential in facilitating the use of UHF scanners in clinical research and for clinical diagnostic purposes, as these reduce siting difficulties. The older PS scanners had larger space requirements and requirements of passive shielding with several tons of steel inside the walls, to reduce the stray field profile of the magnet (7, 20).

Ultra-high field translates into clinical use

In 2015, the International Electrotechnical Commission increased the static magnetic field limit for the first-level controlled operating mode from 4T to 8T. First level controlled operating mode means that there is no significant risk for the subject but medical supervision is required. Operating conditions considered for significant risk evaluation by the U.S. Food and Drug Administration are: main static magnetic field, specific absorption rate (SAR), gradient fields rate of change, and sound pressure level (21). In 2017, one vendor obtained a CE mark for their 7T clinical system. The CE mark indicates that the 7T MR system conforms to health, safety, and environmental protection standards for products sold within the European economic area. Later the same year, the U.S. Food and Drug Administration provided the first clearance for a clinical 7T MR system (22). As Kraff et al. (23) pointed out, the 7T system in Lund was the first in the world that received clearance for diagnostic, clinical imaging. Skåne University Hospital in Lund, Sweden became an in-house manufacturer of the device and performs diagnostic imaging at 7T in selected cases.

Most advantages of ultra-high field MR are by now shown in neuroimaging. For neuroimaging, the increase in SNR and contrast and the enhanced sensitivity to susceptibility have allowed increased high-resolution imaging, which can offer benefits for patients in terms of diagnostics, surgical planning, and therapy monitoring (23, 24). 7T neuroimaging gains higher spatial resolution and contrast in benefit to imaging of grey and white matter disease. Other diseases that benefit from the increased imaging quality of 7T are cerebrovascular disease, multiple sclerosis, malformations of cortical development, and imaging of the subunits of hippocampus in epileptic patients. Ultra-high field functional magnetic resonance imaging (fMRI) with high spatial and temporal resolution allows even weak activation to be detected (6, 24, 25). Furthermore, magnetic resonance spectroscopy

is improved by the more separated metabolic spectra provided by the higher field strength, and is expected to get a boost from 7T (6).

Musculoskeletal MR at ultra-high field has demonstrated clinical benefits in enhancing diagnostic confidence in morphological imaging, especially in cartilage and trabecular bone imaging (23). Ultra-high field multinuclear MR is possible using other nuclei than hydrogen. For instance sodium (Na) MR can be used to measure early molecular changes in osteoarthritis (6).

Ultra-high field imaging has come a long way and clinical applications are increasing for imaging of the brain and musculoskeletal areas (illustrated in **Figure 2**), however, areas still under development in ultra-high field are breast, abdomen, prostate, and spine imaging, which have much to gain from the high spatial resolution and contrast, but RF coils are still an issue. Cardiac imaging has yet another issue – triggering – where the electrocardiography signal is often impaired by magneto-hydrodynamic effects and the beating heart is a challenge in itself (23).

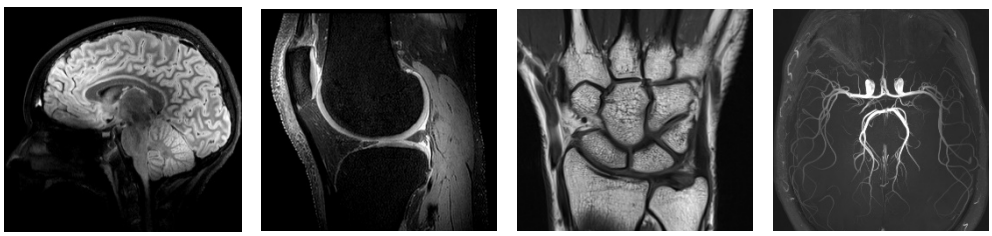


Figure 2.

Images from the 7T MR scanner (Achieva; Philips, Best, the Netherlands) at the National 7T MR facility, Lund University and Skåne University Hospital. Left to right: brain, knee, wrist and intracranial angiogram.

Health effects and short-term effects

Health is a broad concept. The definition of health by the World Health Organization reads “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (26).

In this thesis health effects are in focus. What do health effects mean within the concept of MR? As an example, in the “Non-binding guide to good practice for implementing directive 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)”, the effects of electromagnetic exposure are divided into *sensory effects* – vertigo, nausea, metallic taste, phosphenes (perceived as light

flashes), and minor changes in brain function, and the more severe *health effects* – altered blood flow in limbs, altered brain function, altered heart function, tingling sensation or pain (nerve stimulation), muscular twitches, and disturbed heart rhythm (27).

To avoid confusion; in this thesis health effects will be used in the broader meaning in line with the World Health Organization's definition, and include besides the above mentioned sensory and health effects also for example anxiety and experienced comfort and temperature. The term short-term effects will be used throughout the thesis specifically when discussing sensory effects and health effects occurring inside the magnet as well as when moving into or out of the magnet, e.g. dizziness, inconsistent movement, peripheral nerve stimulation (PNS), headache, nausea, metallic taste, and light flashes.

In addition to the development and possibility of siting ultra-high field scanners in a clinical environment, the MR environment must be safe and well-tolerated by study subjects and patients. It is therefore important to investigate possible relationships between exposure to strong magnetic fields and health effects, and it may be necessary to revise routines related to patient preparation and handling of implants (4, 9). Although study subjects have been shown to tolerate ultra-high field strengths well, they have reported short-term effects such as dizziness, inconsistent movement, nausea, or metallic taste (10-15). These effects have been evaluated in a series of studies (12-15, 28-36) and have also been noted in studies on occupational exposure and effects of the stray field (37-39). While the terms nausea, headache, and metallic taste are self-explanatory, the term inconsistent movement refers to experiencing body movement in a direction other than the actual straight direction through the scanner tunnel, or perception of rotation such as travelling along a curvilinear path through the scanner (31). It can also refer to a feeling of "tipping backwards" (40), of unreality (14), or of insubstantiality (12, 13). Dizziness observed at field strengths less than 8T was proposed to be mediated through a Lorentz force acting in the vestibular system (29, 31, 32, 41). It has also been suggested that magnetic susceptibility of sensory tissues in the vestibular system could be responsible for a magnetic field effect on humans (16, 40). A related short-term effect is optokinetic nystagmus, which is caused by Lorentz force acting on the endolymph of the vestibular labyrinth and pushing on the semicircular canal cupulae (29, 31, 32, 41). Although imaging sub-systems in AS and PS systems of a vendor might nominally be the same (regarding radio frequency and gradient specifications), the magnetic field profile will be significantly different. This may have a bearing on subjects and their perception of some short-term effects such a dizziness or vertigo, nausea or apparent motion during movement in and out of the scanner, but is not expected to impact significantly on the occurrence and strength of other short-term effects such as peripheral nerve stimulation (PNS) or magnetophosphene. Peripheral nerve stimulation is a tingling or (in rare cases)

painful contraction of muscle tissue and magnetophosphene is a phenomenon characterized by the experience of seeing light without light actually entering the eye. The predicted PNS value MR scanners provide, is given as a percentage, where 100% is defined as the level of gradient output at which 50% of humans start to experience PNS (42).

Most of the studies that have evaluated short-term effects have been conducted at sites with passively shielded scanners. Furthermore, the intention to move to diagnostic clinical scanning at ultra-high field means that attention should be paid to nursing care considerations. The aim of nursing care is to achieve as high level of comfort as possible during examination of either study participants or patients, while achieving the best diagnostic quality possible. Ensuring comfort and giving correct and well-balanced information to patients and study participants (**Figure 3**) is an important part of patient-oriented and personalized care (43). Any anxiety level prior to MR examinations was reported in Lo Re et al. by approximately 30% of the subjects, and the main stressor was the uncertainty of the diagnosis, therapy and prognosis (44). Studies investigating anxiety levels prior to the MR examination stress the importance of professionalism of the radiological personnel when they receive and inform the patient, and also during the examination, with emotive involvement and targeted education. This has implications for both patient welfare and image quality (44, 45).

Figure 3.
MR personnel postitions the patient, ensures comfort and gives final information about the examination.

MR safety

Incidents

MR safety related incidents – human injury, material damage and close calls – are increasing as the number of installed MR scanners increases (46). Although already in 1994, Boutin et al. had pointed out the importance of screening procedures before entering an MR scanner room (47), it was not until a ferromagnetic oxygen tank had killed a 6-year-old boy (48) that the first guidelines for MR safety were developed (49). This tragic incident gains even more importance when we consider that the death of the 6-year old boy was preceded by two other projectile-related close calls, neither of which resulted in injury and neither of which was adequately communicated among personnel at the institute in question or led to appropriate safety routines (50).

Incident-reporting systems are of great importance for well-functioning healthcare systems, and they have a crucial alerting role in improving patient safety. Incident reports provide the necessary information to understand the causes of safety-related incidents, also regarding their prevention (51). Prevention of MR safety incidents not only avoids human suffering; it also saves costs and hospital resources (52-54).

The continued development of MR technology requires constant monitoring, and MR safety considerations must accompany these developments. MR safety work and education must always be up to date. The safety incident with fatal outcome for a six-year-old-boy, as referred to above, and the incident described by Clausen et al. (55) 17 years later, in 2018, with an oxygen tank clamping a person to an MR scanner, causing asphyxiation from rapid emission of excessive amounts of oxygen, underscores the sad reality that we never can let our guard down (55). The most important keystones in MR safety are controlled access to MR facilities and assurance of appropriate training (56). However, MR in clinical practice is still not completely safe, and although we are theoretically aware of the three types of magnetic field exposure to be considered for MR safety, there will always be the human factor to consider (**Figure 4**).

Figure 4.
The human factor. Although staged for this photo, ignorance due to lack of training or stress when facing a severe acute situation may easily require the guarding presence of mind of trained personnel to prevent harm.

Electromagnetic fields

For health effects and MR safety, three types of electromagnetic field exposure must be considered: 1 – the static magnetic field, 2 – the gradient magnetic field, and 3 – the radio-frequency field.

1 – The static magnetic field

As clinical super-conductive magnets are strong and always ramped up, the hazard of projectiles, attracted by the static magnetic field, is the most dangerous risk in MR (9, 57). Translational forces on ferromagnetic objects in the body or on ferromagnetic objects brought into the MR scanner room are more dangerous with today's actively shielded magnets than with older, passively shielded magnets since the spatial gradient—the rate of change of the static magnetic field with respect to

distance—is steeper at the vicinity of the bore (2). It is important to always adhere to screening routines and guidelines for prevention of MR related safety incidents (49, 58, 59). This particularly applies to research settings, where researchers have different backgrounds which are not necessarily healthcare-related (60). All equipment and loose objects in the MR environment that might be brought into the MR scanner room must be examined and labelled in accordance with current policies (61). In order to adhere to MR related safety procedures, it is important to keep this in mind already at the planning stage of a new site (49, 62, 63). As long as safety procedures are properly taken into account regarding patients, research subjects, accompanying persons, healthcare workers, and cleaning and maintenance personnel, MR is a safe procedure. For some individuals, when moving through it, the static magnetic field causes earlier discussed short-term effects such as vertigo and nausea, but no serious adverse effects have been reported (4, 10, 16).

2 – The gradient magnetic field

The time-varying gradient magnetic field present during image acquisition may lead to peripheral nerve stimulation, cause acoustic noise, and/or affect implants. When MR safety standards are adhered to, the exposure is kept below risk levels, also avoiding e.g. cardiac stimulation (64). To prevent human injury due to acoustic noise, the study subject or patient must use appropriate hearing protection (57, 65). Induction of electrical currents by the time-varying gradient magnetic field may be harmful and presents potentially fatal risks with implants that are not suitable for MR, for example different types of pacemakers (56, 66, 67).

3 – The radio frequency field

The radio frequency coil transfers energy into the body and can therefore cause thermal heating. Currents are induced in electrically conductive tissue or implants, and heating may occur due to resistance to the current (2). MR safety procedures are aimed at prevention and avoidance of potential thermal risks in electrically conductive materials such as metallic implants, are aimed at ensuring that tissues in humans do not form electrically conductive loops, and are aimed at raising awareness of other factors (e.g. tattoos) that constitute a possible heating risk (49).

MR screening

Considering MR safety, MR screening forms are a very important step to make sure that patients, volunteers, researchers and personnel are MR safe. Extensive screening forms are displayed in Shelock's and Cruse's book (56) and on the American college of radiology (ACR) website (68). The recommendation is to screen twice, once filling out and signing a screening form and then just prior to stepping into the examination room, where the radiographer confirms the patient's

identification and confirms the screening form verbally together with the person to enter the scanner room (69, 70). When a person stands in the doorway of the scanner room, you have to be sure that it is safe to step into the magnetic field. If there is something that can be affected by the static magnetic field, the radio frequency field, and/or the gradient field, it can have a potentially catastrophic outcome. When ultra-high field now is introduced into clinical use, safety concerns rise for subjects with different types of implants within the body, because 1.5 and 3T safe implants are not considered 7T safe due to increased force and torque of the higher static magnetic field. Furthermore, the higher static magnetic field is accompanied by an increased frequency and a shorter wavelength of the RF field which might alter the risk of heating. It does not make things any easier that new implants are continuously introduced, which are not cleared for UHF MR. There is also another aspect to consider when it comes to patients compared to healthy volunteers: the risk benefit assessment. While for a healthy volunteer an unfounded cancellation of an examination primarily might reflect a decreased risk in absence of a benefit, the same scenario for a clinical patient may reflect a missed potential benefit. Uncertainty in decision can lead to refusal of an MR examination, which might have an impact on patient care and treatment decisions (71).

Multi-step screening process

The multi-step screening process at the National 7T MR facility (**Figure 5**) starts, when a subject is scheduled to come for an MR examination.

1. A referral is written by the referring physician when the physician has met the patient, or if it is a healthy volunteer the contact is between the subject and a researcher. Already at this point implants are considered. When the time slot is booked the subject or patient gets a calling form or instructions over the phone, where the screening form is included. The subject is now encouraged to call and tell the MR unit if there might be any issues with implants or shrapnels.
2. When the subject arrives to the MR unit, the written screening form (**Figure 6**) is collected, evaluated and questions are addressed.
3. Thereafter, the subject is shown to a dressing room, where the person changes to hospital clothes and is asked to leave all belongings in a locker. Now the responsible radiographer or researcher evaluates the written screening form again and brings the subject from the waiting room to the area outside the scanner room.
4. As far as up to this point the procedure is the same at all our clinical scanners and similar at many sites in the Swedish and international MR community. However, at the 7T MR scanner at our clinic we have a second screening form

(**Figure 7**), which we use when we verbally interview the subject in the preparation room outside of the scanner room. The documented interview form was designed based on screening forms recommended in the literature (58, 49, 56) and is based on the authors' personal communication with other 7T facilities.

5. As the last step of the multi-step safety procedure, the subject passes a ferromagnetic detector built into the doorway to the 7T MR scanner.

As a prerequisite for decision making in the multi-step screening process, MR safety training includes: general knowledge of safety risks and their relationship to the three main electromagnetic fields in MR; getting familiar with the screening procedures and being able to perform these; being able to contact MR responsible personnel for risk assessment questions, but also to become acquainted with the local 7T MR safety committee procedures and its documentation and updated on-site website listing implants and equipment previously tested to be allowed access to the 7T MR scanner room. The local 7T MR safety committee includes radiologists, MR radiographers and MR physicists and allows multidisciplinary MR safety risk benefit assessments. Further, general safety instructions and education regarding acute evacuation from the facility, alerting of the hospitals resuscitation and emergency medical team, fire alarm procedures, quenching the magnet (how the magnetic field is brought down in case of emergency) are also included in the training.

Figure 5.
The multi-step screening procedure at the National 7T MR facility, Skåne University Hospital

SCREENING FORM

For Magnetic Resonance (MR) procedures

Name:	Subject ID:
Weight (kg):	Height (cm):

If any question is answered by **YES** you **MUST** contact us as soon as possible before the examination, even if you have had an MR examination previously.

	YES	NO
Have you ever had any head/brain or cadiac surgery? If yes, what type of surgery? When and where?	☐	☐
Do you have any type of implant, foreign body, electrical/mechanical equipment or electrode in your body? (e.g. pacemaker, pump, metal clips, shrapnel, hearing aid, replacement joint, shunt valve)? Dental fillings is not a contraindication. If yes, what type and where?	☐	☐
Do you hava a history of renal (kidney) disease?	☐	☐
For female patients: Are you pregnant?	☐	☐

You **must remove all** metal objects, makeup, jewellery, false teeth, body-piercing, hearing aids, insulin pump etc.) **before** entering the magnet hall.

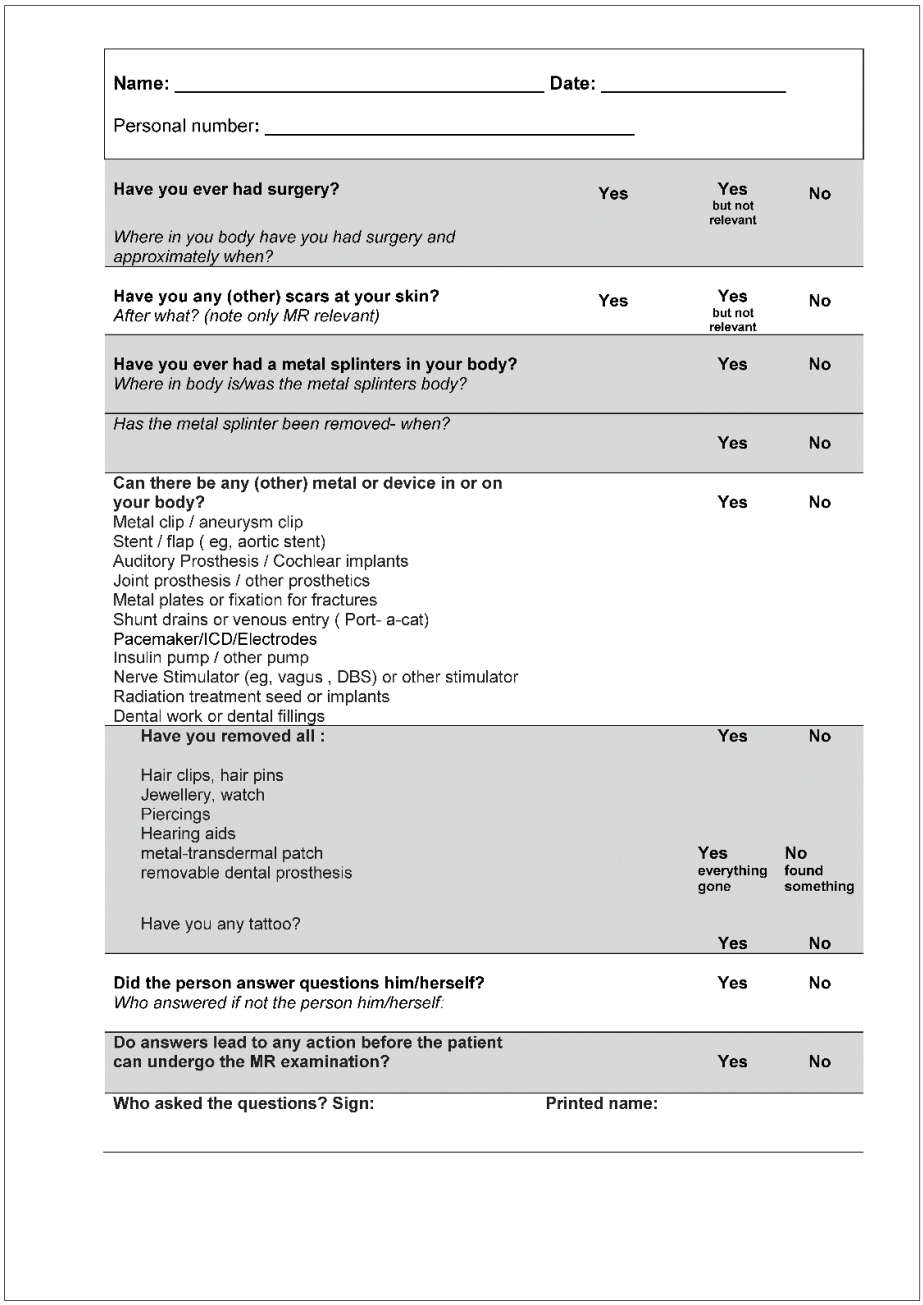
Signature:	Date:

Please contact us if anything is not clear.
Tel: +46 46 177035, Mon-Thu 9.00-11.00 and 13.00-15.00. Fri 09.00-11.00.

For accompanying person, please turn

Frågeformulär, polikliniska, eng, Version 1, Sid. 1(2), 2014-04-14
Författat och godkänt av MR-ansvarig fysiker, MR-ansvarig sjuksköterska och MR-ansvarig läkare
VO Bild och Funktion, Lund

Figure 6.
Screening form 1 at the National 7T MR facility, Skåne University Hospital



Name: _____ **Date:** _____

Personal number: _____

Have you ever had surgery? *Where in you body have you had surgery and approximately when?*	**Yes**	**Yes** but not relevant	**No**
Have you any (other) scars at your skin? *After what? (note only MR relevant)*	**Yes**	**Yes** but not relevant	**No**
Have you ever had a metal splinters in your body? *Where in body is/was the metal splinters body?*		**Yes**	**No**
Has the metal splinter been removed- when?		**Yes**	**No**
Can there be any (other) metal or device in or on your body? Metal clip / aneurysm clip Stent / flap (eg, aortic stent) Auditory Prosthesis / Cochlear implants Joint prosthesis / other prosthetics Metal plates or fixation for fractures Shunt drains or venous entry (Port- a-cat) Pacemaker/ICD/Electrodes Insulin pump / other pump Nerve Stimulator (eg, vagus , DBS) or other stimulator Radiation treatment seed or implants Dental work or dental fillings		**Yes**	**No**
Have you removed all : Hair clips, hair pins Jewellery, watch Piercings Hearing aids metal-transdermal patch removable dental prosthesis		**Yes**	**No**
		Yes everything gone	**No** found something
Have you any tattoo?		**Yes**	**No**
Did the person answer questions him/herself? *Who answered if not the person him/herself:*		**Yes**	**No**
Do answers lead to any action before the patient can undergo the MR examination?		**Yes**	**No**
Who asked the questions? Sign:	**Printed name:**		

Figure 7.
Screening form 2 at the National 7T MR facility, Skåne University Hospital

As recommended, implants, devices or foreign bodies need to be evaluated specifically for safety concerns at 7T, prior to the examination, even if they are cleared for lower field strengths such as 1.5T and 3T (22). At our National 7T MR facility we have a 7T MR safety committee with physicists, radiographers, and radiologists. The committee evaluates safety issue brought forth by personnel and documents the decision. The implant approval procedure is in line with international recommendations (72). The documentation is further processed at least once a year and if possible, a general recommendation is added to our internal safety regulations (web page accessible by all personnel). After the general recommendation, the implant or device does not have to go through the documentation process again, as long as potentially stated restrictions are met. This safety process can be initiated during any phase of the multi-step screening process.

Risk and benefit

MR is known as a safe imaging method, with no use of ionizing radiation. However, the key to safe scanning is to understand the risks and always adhere to safety regulations (2) but also to acknowledge potential benefits. At any MR facility, it is the responsibility of the institution that installs an MR scanner to ensure patient, volunteer, and personnel safety before and during the examination, although safety might be more challenging for UHF systems (22).

Even if an implant has previously been tested and been considered safe for 1.5 and 3T, it is necessary to test the same object at 7T, as explained earlier. The 7T community is just in the beginning of this process, and this work is urgently needed (69). A few studies have been published regarding implants in 7T showing that it can be justified and is safe to scan subjects with certain implants and tattoos (19, 73, 74).

To be able to examine more patients with implants at the 7T – which is required when 7T now translates into clinical use – more testing, information, and documentation is essential to obtain a safe MR setting (56). The process of the risk benefit assessment is the same for all field strengths, but the benefit might be different regarding patients versus healthy volunteers as explained earlier. Implants may also cause more severe artefacts than at lower field strengths, which needs to be taken into account by the radiologist (74). However, increased image quality and diagnostic information usually counterbalances drawbacks of the ultra-high field and diagnostic image quality is to be considered in terms of risk-benefit analyses.

To obtain the best possible image quality and to increase patient compliance, it is of great importance that the radiological personnel act professionally and at the best interest of the patient (44, 45). Communication with and monitoring of the patient or volunteer should be maintained and frequent to enable them to indicate any

discomfort during the examination (19, 75). Discomfort may not only be interpreted as such, but can also indicate more extensive peripheral nerve stimulation (PNS) or more severe risks such as misplaced hearing protection or heating. Discomfort might potentially affect benefits such as image quality when causing for example motion.

Nursing care

Nursing care should permeate the subject's whole visit at the MR facility. As the first step after arrival, when the MR safety screening form is evaluated, nursing care should be present in a warm, welcome and medical privacy. If this continues through the multi-step MR screening process (described earlier), professionalism provides a sense of security for the subject. When the subject is placed on the scanning table, nursing care needs to assure comfort and compliance. Comfort is essential for being able to lie still, which in turn is essential for compliance and image quality. Further, MR safety with padding to avoid burns is merged with nursing care for comfort. To make sure that the alarm bulb is working the subject is asked to squeeze it and both the personnel and the subject are assured that communication can be initiated whenever necessary. During the MR examination nursing care continues through the intercom. In-between individual scans throughout the session, personnel talk to the person inside the scanner to make sure everything is all right. At any time, but especially when operating the system is especially demanding, as for example when dealing with UHF MR, it is advantageous to have two trained staff members participating in the examination, to assure correct handling of the system without losing focus on the subject in the scanner. This is also something for the management to consider when planning for staffing. In MR safety international guidelines for MR workers it is recommended not to work alone when working with human subjects (76). After the scanning, especially at 7T, it is important for the subject to have some time to cope and rest if necessary, as dizziness is common after moving through the high magnetic field.

Implications for compliance in nursing care were pointed out in Kalisch and Faan (77) addressing the necessity of personnel being engaged in both collection and analysis of such data, but also the importance of creating a culture of quality and safety that ensures attention to detail and honest reporting (77). Missed nursing care in the literature might be comparable with missed MR safety compliance. The causes of missed nursing care were summarized in three themes by Kalisch and Xie (78); staffing resources, material resources, and communication (78). Causes of missed nursing care were identified in the literature as caregivers' emotional or physical exhaustion or fatigue, inadequate supervision of nursing assistants, interruptions and multitasking, a lack of cues or care reminders, and inadequate leadership support (79).

Aims

Specific aims of the individual papers were:

Paper I: To evaluate the occurrence and the strength of short-term effects, that were experienced by study subjects in an actively shielded 7T MR, to discuss differences compared to results in literature from passively shielded 7T scanners, and to outline possible healthcare strategies that might improve patient compliance.

Paper II: To investigate the quantity of, the intensity of, and subjective experiences from the effects of 7T MR in a large scale study, focusing on patient comfort and compliance.

Paper III: To survey MR safety incidents that occurred over a 12-month period; to assess incident severity and to evaluate confidence of MR personnel in incident-reporting mechanisms. Further to compare with CT personnel as a control group.

Paper IV: To evaluate compliance with a multi-step MR safety screening routine at a 7T MR facility and the benefit of a documented structured screening interview prior to entrance to the MR scanner room in addition to a less comprehensive written screening at arrival.

Method

Ethics

The studies for paper I and II were approved by the appropriate ethics committee (Swedish ethical review authority) (entry nos. 2015/434 and 2016/126) and informed written consent was obtained from all the subjects.

The study for paper III was approved by the appropriate ethics committee (entry nos. 2014/867). Written informed consent was not required for this study as waived by the ethics committee, and withdrawal from the study after submission of the web-based questionnaire was not possible, as data were collected anonymously.

The study for paper IV was approved by the appropriate ethics committee (entry nos. 2015/437) also waiving the requirement of informed consent.

All studies were performed in line with the Helsinki Declaration guidelines, 2013 Nov 27;310(20):2191-4.

The scientific guarantor for all publications in this thesis is the main supervisor Professor Isabella M Björkman-Burtscher. All co-authors of included publications declare no relationships with any companies, whose products or services may be related to the subject matter of the articles.

Subjects and MR system

Subjects for papers I and II were recruited at the National 7T MR facility in Lund, Sweden. After undergoing a 7T MR examinations for other purposes, subjects were recruited and asked to fill in a web-based questionnaire on subjective experiences related to the examination.

Subjects in paper III were recruited among personnel working with MR and/or CT in Sweden. MR vendors provided a list of installed bases in Sweden and personal contact was made with each site to identify a person responsible for MR and/or CT who could distribute information about the study and post a link to the questionnaire. The web-based questionnaire (REDCap; research electronic data capture;

http://project-redcap.org) was used to collect data over a 6-month period. Personnel scanning to any degree with MR and/or CT were invited to participate, thus the survey targeted primarily MR and CT radiographers.

Data included in paper IV were collected from MR safety screening forms and the radiological information system (RIS) of subjects who had been scheduled for a 7T MR examination at the National 7T MR facility during a period of four years (2016-2019) and who had actually accessed the facility.

No MR examinations were performed for the sake of studies included in this thesis.

However, in papers I, II, and IV subjects who had undergone an MR examination (papers I and II) or were scheduled to undergo an MR examination (paper IV) were included. These examinations were conducted in first-level controlled operating mode, not exceeding the specific absorption rate (SAR) limit of whole-body 4 W/kg or head 3.2 W/kg, on an actively shielded 7T MR scanner (Achieva, Philips, Best, the Netherlands) with the following specifications: gradient system with a combination of maximum amplitude 40 mT/m and maximum slew rate 200 mT/m/ms, or maximum amplitude 60 mT/m and maximum slew rate 100 mT/m/ms; tunnel diameter 58 cm; length of magnet 3.3 m; a maximum spatial field gradient (dB/dz) of the stray field of 7.86 T/m at 130 cm from isocenter. The 2Tx/32Rx Nova head coil (Nova Medical, Wilmington, MA, USA) was used for brain examinations, 1Tx/28Rx Knee Coil QED (Quality Electrodynamics, Mayfield Village, OH,USA) was used for the knee examinations, 1Tx/16Rx wrist array (RAPID MRI International, Columbus, OH, USA) was used for the wrist examinations, 1Tx/8Rx Breast array (RAPID MRI International, Columbus, OH, USA) was used for the breast examinations, and 1Tx/8Rx C-spine coil (Life services, Minneapolis, MN, USA) was used for the c-spine examination.

In paper III, personnel answering the web-based questionnaire worked with a variety of different MR scanners (CT scanners for the control group) as the participants of the study were located at hospitals and clinics all over Sweden.

Data collection

Paper I and II

After undergoing a 7T MR examination for other purposes, subjects filled in a web-based questionnaire. Data collected were demographic data on gender (male/female) and age (years); session parameters noted by operator on length of examination (min), body part examined and orientation of the body in the field (head first/feet first); short term effects and comfort and experience parameters as well as

information on self-estimated sensitivity regarding motion sickness (kinetosis) according to **Table 1**. In addition, predicted peripheral nerve stimulation (PNS) values were extracted from log files from the scanner, and from each examination the highest predicted PNS value was used in the analysis for the latter 83 of the 154 examinations in Paper I, as a trend of high PNS occurrence and strength was observed early on during data collection. In paper II highest predicted PNS values were collected from 627 examinations (66%). The predicted PNS value is given as a percentage, where 100% is defined as the level of gradient output at which 50% of humans start to experience PNS (42).

Table 1.
Evaluated short term effects, comfort and experience parameters as well as self-estimated sensitivity regarding motion sickness (kinetosis) and used grading scales in papers I and II.

Parameter	Evaluated for	Occurrence	Number or quantity	Intensity
Dizziness Inconsistent movement Nausea Headache Metallic taste	in, inside, out, and outside the scanner	**Paper I** Yes/no **Paper II** Yes/no	**Paper I** absolute VAS values (a) adapted VAS values (b) **Paper II** 6-point Likert scale (c)	**Paper I** absolute VAS values (a) adapted VAS values (b) **Paper II** 6-point Likert scale (c)
PNS Light flashes	during the examination			
Body temperature Room temperature	before, during, and after the examination			**Paper I** bipolar Likert VAS scale (d) adapted bipolar Likert VAS scale (e) **Paper II** 7-point adjectival scale (f)
Anxiety	for patients and healthy volunteers			**Paper II** 6-point Likert scale (c)
Scanner noise Communication system	during the examination			**Paper I** adjectival VAS scale (g) **Paper II** 5-point adjectival scale (h)
Willingness to undergo a future 7T MRI	after the examination			
Kinetosis	unrelated to examination		**Paper I** absolute VAS values (a) adapted VAS values (b) **Paper II** 6-point Likert scale (c)	

(a) absolute VAS values 0–100; (b) adapted VAS values where absolute values were grouped as: none = 0; very little = 1-20; little = 21-40; moderate = 41-60; much = 61-80; very much = 81-100; (c) six-point Likert scale, none, very little, little, moderate, much, and very much; (d) bipolar Likert VAS scale 0-100; (e) adapted bipolar Likert VAS scale; 0-23 = uncomfortably cold; 24-47 = cold; 48-53 = comfortable; 53-76 = warm; and 77-100 = uncomfortably warm; (f) seven-point adjectival scale, uncomfortably cold, cold, slightly cold, comfortable, slightly warm, warm, and uncomfortably warm; (g) adjectival VAS scale, 0 = strongly agree; 1-20 = agree; 21-40 = mildly agree; 41-60 = mildly disagree; 61-80 = disagree; 81-100 = strongly disagree; (h) five-point adjectival scale, strongly agree, agree, neither agree nor disagree, disagree, and strongly disagree. (In paper II this was wrongly presented as a six-point scale in the method part.)

Paper III

Personnel scanning to any degree with MR and/or CT and filling in the distributed web-based questionnaire provided the following demographic data: age; gender; full-time (full time = 40 hours/week) or part-time work; percentage of full time dedicated to work with MR, CT, other modalities (e.g. ultrasound, conventional radiology), or administration; modality experience (years); number and type(s) of installed scanners; and patient demographics at site (e.g. clinical, research, level of care burden).

Data on safety incidents focused on human injuries, material damage, and close calls. The participants stated whether they were aware of any safety-related incidents that had occurred at their hospital during the last 12-month period before participation in the survey, including a voluntary free-text description of the incidents, to classify incidents and exclude double reports. To allow protection of the integrity of the participants and to decrease the risk of under reporting due to fear of recognition, free-text comments were not mandatory. This issue was emphasized during ethical evaluation of the study design. Participants were also asked if they were confident that any safety incidents that might have occurred at their workplace would have come to their attention (confidence in incident-reporting mechanisms). Questions on safety were repeated for MR and CT for comparison, allowing participants working with both modalities to fill in a complete set of safety questions for both modalities.

Risk assessment of severity of human injuries were performed based on the free text comment. The score (**Table 2**) was based on the National Patient Safety Improvement Handbook (80), and only considers human injuries. Mainly immediate consequences were expected to be mentioned in the free text comments, since personnel at radiology departments usually do not have the opportunity to follow-up on long term outcome after incidents. This might however differ for very severe incidents, where feedback loops are expected to be more efficient, not the least due to possible legal consequences. Further, all safety incidents were scored with a potential severity score defining the potential worst-case scenario outcome of a similar incident.

Scoring was performed during a consensus discussion regarding each safety incident by the head MR safety physicist (Johan Olsrud), the head MR safety research radiographer (Titti Owman), the responsible research radiographer (Boel Hansson), and the Principal Investigator of the study, a neuroradiologist with 20 years of experience (Isabella Björkman-Burtscher).

In Sweden there is no national register for safety incidents, and hospitals are only encouraged to report any preventable serious incidents that have or might have led to human injury to the health and social care inspectorate, a government agency.

Table 2.
Risk assessment severity score for human injuries and potential severity scores for all safety incidents reported and further explained in a free text comment (based on the National Patient Safety Improvement Handbook (80))

Score	Definition
1	minor (discomfort or insignificant injury)
2	intermediate (transient sensory, motor, physiological, intellectual, or mental disability; extended care episode; or increased care level)
3	significant (persistent moderate sensory, motor, physiological, intellectual, or mental impairment; extended care episode; or increased care level)
4	catastrophic outcome (death, persistent major sensory, motor, physiological, intellectual or mental disability)

Paper IV

A multi-step MR safety screening routine was implemented at the National 7T MR facility prior to start-up of the facility (illustrated in the background (**Figure 5)**).

Step-1, referral and booking process: A referral including the type and purpose of the examination, the clinical or research question, and relevant patient history and contraindications is sent to the facility by a physician or a research principal investigator. Booking of the patient is combined with a written invitation including a written screening form (SF1 (**Table 3**)) or – for short notice appointments – a telephone call including an overview screening interview aligned with SF1 and part of SF2. Subjects are encouraged to contact the MR facility in advance to the visit, if any screening form questions are answered with yes or in case of any questions. If of relevance, contact and information is documented in the radiological information system (RIS).

Step-2, written screening form (SF1 (**Table 3**)): Upon arrival, the subject is required to present or fill in SF1, the standard screening form for all MR scanners (1.5T to 7T) at the institute, and questions arising from the information given or asked by the subject are addressed. SF1 reflects a common national screening approach with short screening forms covering some major safety risks and counteracting question fatigue or ignorance, leaving large responsibility to the individual personnel performing the MR screening process.

Step-3, change of clothes: all subjects are required to change from private clothing to MR approved gowns (only exceptions were the patient's own panties/underpants and socks).

Step-4, structured interview documented on screening form 2 (SF2 (**Table 3**)): After again checking SF1 the structured screening interview is performed directly outside the MR scanner room and documented on SF2. The design focused on repetition, rephrasing and extension of questions from SF1 to rouse the awareness of importance in subjects but also to recall memory. Further, SF2 was designed to detect if the interviewer just negates any safety risks by ticking of the answer "no" to all questions – such documentation was graded as "incorrectly filled out" during the analysis.

Step-5, ferromagnetic detector screening: is performed as a final step when entering the MR scanner room through a ferromagnetic detector built into the doorway (Ferro Alert Halo II plus, Kopp Development Inc. Florida, US).

It is the responsibility of the radiographer or researcher performing the scan to assure that MR safety screening has been performed correctly prior to the scan.

Table 3
Questions in screening forms 1 (SF1) and 2 (SF2)

Q	**Questions in written SF1**	
1	Have you ever had any head/brain or cardiac surgery? When, where in your body, what (free text)?	yes/no
2	Do you have any type of implant, foreign body, electrical/mechanical equipment or electrode in your body? (e.g. pacemaker, pump, metal clips, shrapnel, hearing aid, replacement joint, shunt valve)? Dental fillings is not a contraindication. When, where in your body, what (free text)?	yes/no
3	Do you have a history of renal (kidney) disease (free text)?	yes/no
4	For female patients: Are you pregnant	yes/no
	Information to patient: you must remove all metal objects, makeup, jewellery, false teeth, body-piercing, hearing aids, insulin pump etc. before entering the magnet hall.	
Q	**Questions in documented interview SF2**	
1	Have you ever had surgery? Where in your body and when (documented by personnel if considered relevant for the ongoing screening process)? (free text)	yes/no/not relevant*
2	Have you any (other) scars in your skin? Why? (free text)	yes/no/not relevant
3.1	Have you ever had a metal splinter in your body? Where? (free text)	yes/no
3.2	*Has the metal splinter been removed? When?* (free text)	yes/no
4	Can there be any (other) metal or device in or on your body? Metal clip/aneurysm clip; stent/flap (e.g. aortic stent); auditory prosthesis/other prosthetics; metal plates or fixation for fractures; shunt drains or venous entry (port-a-cat); pacemaker/ICD/electrodes; insulin pump/other pump; nerve stimulator (e.g. vagus, DBS) or other stimulator; radiation treatment seed or implants; dental work or dental fillings. (free text)	yes/no
5.1	Have you (during step 3) removed all: hair clips, hair pins, jewellery, watch , piercings, hearing aids, metal-transdermal patch, removable dental prosthesis	yes/no
5.2	*Check of 5.1. by responsible personnel as far as possible* (free text)	yes/no
6	Have you any tattoo? (free text)	yes/no
7	Did the patient answer questions him/herself? Who if not? (free text)	yes/no
8	Do answers lead to any action before the patient can undergo the MR examination? (free text)	yes/no
9	Who asked the questions? Signature of personnel	

*not relevant: judged as no interest from an MR safety point of view.

MR safety screening documentation – SF1, SF2 – was evaluated for compliance with routines and MR safety risks were identified in the screening steps and compared with information on whether examinations were actually performed or why they were not performed. Data analysis included descriptive statistics of the study population (age and gender), performed screening steps (compliance) with identification of missing documents (SF1 or SF2), missing fields in SF1 and SF2, and incorrectly filled out documents. Further, types of surgeries and types of implants and accessories documented during MR safety screening (including additional information in RIS) were categorized and additional information identified in SF2 compared to SF1 was further analysed. Also questions regarding tattoos, renal disease and pregnancy were evaluated. Further 7T MR safety committee decisions were analysed during the study period.

Statistics

Statistical analysis used in the individual papers are set forth in **Table 4**.
A p-value < 0.05 was regarded as being statistically significant. Statistical analysis was mainly supported by co-authors P. Höglund in papers I, and III and M. Nilsson in paper II.

Table 4.
Data collection and statistical analysis used for the individual papers

	Paper I	Paper II	Paper III	Paper IV	Examples of analyse
Descriptive statistics	●	●	●	●	Distribution of data in the cohorts
McNemar´s chi-square test			●		Confidence of safety incidents MR vs CT
Mann-Whitney *U* test	●	●	●		Differences were compared of continuous variables
Wilcoxon signed-rank test	●		●		Paper I: comparison of static vs motion Paper III: comparison of work hours MR vs CT
Pearson´s chi-square test	●				Pairwise comparisons if counts > 5
Fisher´s exact test	●				Pairwise comparisons if counts < 5
Spearman rank correlation test		●			Motion sickness and PNS vs quantity and intensity of effects
Kendall rank correlation test	●				Bivariate correlation if ranks were far from each other
Linear regression analysis	●				Motion sickness correlation to nausea, dizziness and inconsistent movement
Mixed-model analysis	●				Short-term effects´ movement and orientation
Logistic regression	●				Dependence of strength and occurrence of twitching on the highest predicted PNS
T-test		●			Anxiety levels between the first and second 7T examination

Results

Study subjects

An overview of the study subjects for the individual papers is shown in **Table 5**.

Table 5.
Overview of the study subjects

		Paper I	Paper II	Paper III	Paper IV
Subjects (n)	all	124	801	529	1819
	female	49	376	415	935
Age, mean (range) years	all	34 (21-64)	35 (14-82)	45 (23-66)	34 (12-87)
	female	34 (28-61)	35 (14-82)	46 (23-66)	33 (12-87)
	male	34 (21-64)	35 (14-81)	43 (25-65)	35 (13-84)
Patient examinations (n)		na	272	na	na
Research examinations (n)		na	682	na	na
MR workers (n)		na	na	345	na
CT workers (n)		na	na	392	na
MR and CT workers (n)		na	na	208	na

na, not applicable

In paper III, 345 of the participants worked part-time or full-time with MR, 392 worked part-time or full-time with CT; 137 with MR but not CT, 184 with CT but not MR, and 208 with both MR and CT. The estimated response rate of MR workers was approximately 60%. The survey covered most MR scanners in the country, as all large hospitals were covered and the majority non-covered by the survey (n = 11) were small private MR facilities (n = 7). The participants working with MR in the study therefore worked at 81 hospitals, entailing approximately 225 MR scanners; and the participants working with CT worked at 84 hospitals with 253 CT installations.

Paper I and II

Short-term effects

In paper I and II the numbers of participants who experienced dizziness, inconsistent movement, nausea, headache, and metallic taste are shown in **Table 6**.

In paper I dizziness and inconsistent movement showed the highest visual analogue scale (VAS) values regarding strength. We tested whether or not there was occurrence of dizziness, inconsistent movement, nausea, headache, and metallic taste in all possible pairwise comparisons in relation to movement into or out of the scanner and position in or outside the magnetic field (in, out, inside, and outside). All differed significantly ($p < 0.005$; Pearson chi-square test, or Fisher's exact test if counts < 5), showing that experiencing a short-term effect when going into the magnet did not necessarily mean that the experience would be the same when going out of the magnet. Further, Wilcoxon signed rank test showed short term effects to occur significantly more often during motion (in and out) compared to static location (inside and outside the scanner) for dizziness, inconsistent movement, and nausea ($p < 0.01$) but not for headache ($p = 0.2$) and metallic taste ($p = 1$).

Table 6.
Occurrence of short term effects in papers I and II, n subjects (%)

Short-term effect	Paper I	Paper II
Dizziness	130 (84%)	771 (81%)
Inconsistent movement	108 (70%)	648 (68%)
Headache	81 (52%)	386 (40%)
Nausea	81 (52%)	304 (32%)
Metallic taste	66 (43%)	111 (12%)
Peripheral nerve stimulation	103 (67%)	598 (63%)
Light flashes	35 (23%)	78 (8%)

In paper II when comparing patients (n = 272) with healthy volunteers (n = 682), patients had significantly more often and more intense headache ($p < 0.01$; moving in, inside, moving out, or outside of the scanner) and metallic taste ($p < 0.01$; outside the scanner) but less intense dizziness ($p = 0.01$; outside) compared to healthy volunteers. In paper I, 113 study subjects reported having any sensitivity to motion sickness, with a median self-estimated VAS value of 33 (range 1-100). Linear regression analyses using the self-estimated sensitivity for motion sickness as independent variable and the strength of short-term effects as dependent variables were significant for nausea ($p < 0.001$), but not explaining the data variability well ($r^2 = 0.086$). Linear regression analyses were not significant for dizziness ($p = 0.064$; $r^2 = 0.023$) or inconsistent movement ($p = 0.066$; $r^2 = 0.024$).

Study participants in paper I experienced peripheral nerve stimulation (PNS) in 67% (n = 103) of research examinations. There was no difference in occurrence of PNS between examinations performed head-first (118 brain examinations) and examinations performed feet-first (25 knee examinations) ($p = 0.27$, Mann-Whitney U-test). Torso, hand, and arm were the body parts mainly affected (occurrence) by twitching when examined head-first. PNS affected only extremities when examined feet-first with a predominance of the lower extremity. For 598 of the examinations (63%) in paper II, the subjects reported that they had experienced PNS. The data on the quantity and intensity of PNS and how these were experienced are summarized in **Figure 8**. Spearman's rank correlation showed a significant ($p < 0.001$) strong correlation between both the quantity ($\rho = 0.87$) and the intensity ($\rho = 0.90$) of PNS events associated with experiencing of such PNS events. Furthermore, there was a significant ($p < 0.001$) and very strong correlation between the quantity and the intensity of the PNS events ($\rho = 0.93$), but there was a significant but only very weak correlation between highest predicted PNS value ($\rho = 0.19$) associated with the experience of PNS; there also was, a significant ($p < 0.001$) but weak correlation between the highest predicted PNS value for each examination—for both quantity of PNS ($\rho = 0.20$) and intensity of PNS ($\rho = 0.23$).

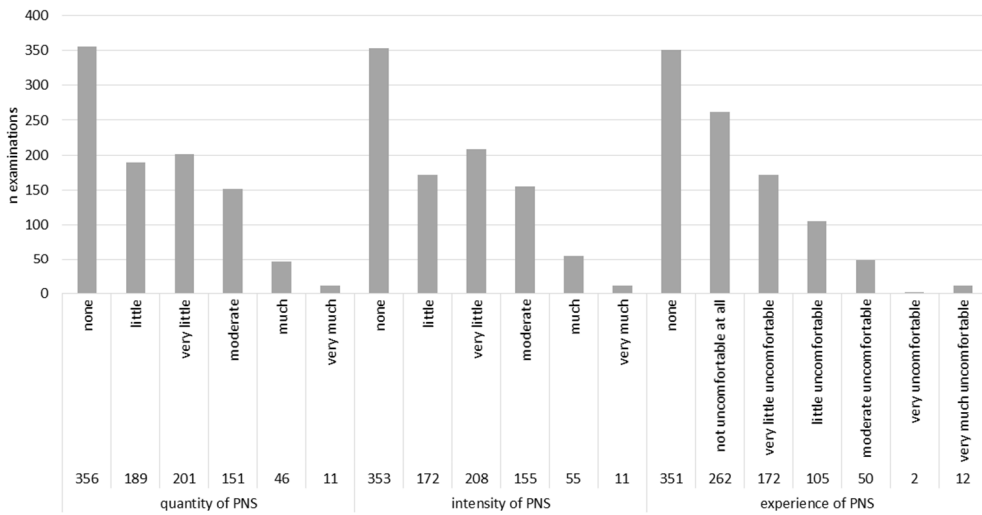


Figure 8.
Quantity, intensity and, experience of PNS in paper II

In paper I study participants experienced magnetophosphene in 23% (n = 35) of research examinations. There was no difference in occurrence of magnetophosphene between examinations performed head-first (118 brain examinations) and examinations performed feet-first (25 knee examinations) (p =

1.0, Mann-Whitney U-test). As expected there was no correlation between the occurrence of PNS and magnetophosphene ($p = 0.062$, Kendall rank correlation).

Temperature, scanner noise, and communication

The temperature in the scanner room was generally reported as being comfortable in paper I (76%). Otherwise, study participants tended to report that the scanner room temperature was lower than comfortable. The scanner room temperature was generally experienced as being more comfortable before than during examinations in paper II. The change in room temperature most commonly reported was a change towards warmer room temperature (338 subjects (35%), as compared to 107 subjects who reported experiencing a decrease in room temperature). Experience of temperature did not differ between patients and healthy volunteers.

Body temperature was also generally reported as being comfortable during the examination in paper I and paper II (70%, 51% respectively). Study participants felt a subjective decrease in body temperature in 12% of the research examinations ($n = 18$) and a subjective increase in 18% ($n = 28$) in paper I and also 12% ($n = 119$) felt subjective decrease but 40% ($n = 374$) subjective increase in paper II. These temperature changes were mainly reported to be local, with decreased temperature reported in peripheral parts of the extremities such as the feet and hands and increased body temperature in the head/face, torso, and arms in both paper I and II. Experiencing an increased body temperature was often associated with perception of a temperature increase in the face or head and upper extremities (hands and arms), whereas subjects who felt a decrease in body temperature mainly reported having cold feet.

In paper I the scanner noise levels were well tolerated, and the communication system was reported to function well during the examination. The noise levels were significantly more disturbing ($p < 0.001$) and communication problems were experienced more frequently ($p = 0.001$) when study participants were scanned head-first than when they were scanned feet-first (Mann-Whitney U-test). Of the subjects 95% ($n = 147$) reported that they had felt well-informed and had had good contact with the personnel running the procedure prior to the examinations and 88% ($n = 135$) of them during the examination. In paper II data on acceptability of maximum scanner noise levels, functioning of the communication system, view of information and contact with personnel show that patients and healthy volunteers in 80% to 99% of the examinations agreed or strongly agreed on positive perception of these aspects.

Compliance, comfort and anxiety

The results in paper I showed a high willingness to undergo a future 7T examination both regarding examination as a study participant (90%) and as a patient (96%), with no significant gender difference (for healthcare purposes, $p = 0.29$; as a research subject, $p = 0.49$).

The statement that the total experience of the MR examination was comfortable in paper II, was strongly agreed with or agreed with by 600 subjects (63%), whereas 246 (26%) neither agreed nor disagreed, and 108 (11%) disagreed or strongly disagreed. Further, there was a significant difference in the comfort rate between patients and healthy volunteers ($p = 0.007$). Healthy volunteers experiencing the 7T examination as more comfortable compared to patients – 57% of patients and 65% of healthy volunteers agreeing or strongly agreeing with the statement that the total experience of the MR examination was comfortable. Willingness to undergo future 7T examinations for research purposes was 82% and for clinical purposes 93%. In paper II, an analysis was conducted of subjects who had experienced a previous MR examination, — which was true for 644 of the examinations (77%). These subjects rated the 7T MR experience as worse than previous MR examinations in 27% ($n = 174$), 50% rated the examination experience as the same as previous MR examinations ($n = 323$), and 23% as being a better experience than previous MR examinations ($n = 147$).

In paper II anxiety level was analysed. The difference in anxiety level reported by patients and healthy volunteers was significant with a higher anxiety level for patients prior to the 7T MR examination (Mann-Whitney U-test, $p = 0.03$), where the term “patients” covers those who underwent clinical scans and those who were included in a clinical, disease-specific research study.

Paper III

Safety incidents and risk assessment

Altogether, 200 MR safety incidents and 156 CT safety incidents were reported by the 529 participants. The numbers of human injuries, material damages, and close calls related to MR and CT are detailed in **Table 7**, together with information on multiple reporting of specified incidents, the number of participants reporting the incidents, the number of hospitals affected, and the number of participants working with the modality in question at these hospitals. Exclusion of multiple reporting, was performed based on evaluation of free text comments, and reduced the number of specified incidents by a mean of 33% for MR and 19% for CT (**Table 7**).

Table 7.
Safety incidents reported by 345 MR workers at 81 hospitals and 392 CT workers at 84 hospitals

Safety incident and modality evaluated		Reported incidents (n_{tot}; n_{spec}; n_{spec_ex})	Hospitals (n) with reported incidents	Participants not reporting incidents, n (%)	Participants n (%) working at hospitals			
					with reported incidents			without reported incidents
					total	reporting an incident	not reporting incidents	
HI	MR	21; 18; 11	11	326 (94)	87	19 (22)	68 (78)	258
	CT	64; 30; 25	23	359 (92)	177	33 (19)	144 (81)	215
MD	MR	50; 34; 21	15	308 (89)	116	37 (32)	79 (68)	229
	CT	39; 18; 14	15	369 (94)	152	23 (15)	129 (85)	240
CC	MR	129; 93; 65	33	263 (76)	201	82 (41)	119 (59)	144
	CT	53; 15; 12	17	369 (94)	145	23 (16)	122 (84)	247
Total	MR	200; 145;97	37	306 (89)	220	39 (18)	181 (82)	125
	CT	156; 63; 51	34	329 (84)	248	63 (25)	185 (75)	144

Human injury, HI; material damage, MD; close calls, CCs; n_{tot}, *total* number of reported incidents; n_{spec}, number of incidents further *specified* with free-text comment in questionnaire; n_{spec_ex}, number of *specified* incidents *excluding* multiple reporting (further detailed in Table 3), as identified by hospital affected and description of incident. Table reprinted with permission, Hansson et al. (81)

The pattern of incidents that were further specified by participants and evaluated after exclusion of multiple reporting, differed between MR (n = 97) and CT (n = 51). MR users focused mainly on incidents related to the static magnetic field, the radio frequency field, and the gradient magnetic field (projectiles, implants and burns) (n = 92), whereas CT users focused on radiation issues (n = 3) and complications related to application of contrast media (n = 12), a topic that was not at all touched upon by any of the MR users. Incidents related to ergonomics (n = 41), with a mixture of heavy lifts of equipment or patients, and clamping and squeezing incidents involving equipment, affecting patients and personnel were reported for both modalities but more often by CT users (n = 36) than by MR users (n = 5). Material damage and close calls were more often reported by MR users than by CT users, however, human injuries were more common for CT.

Although not specifically requested, participants who used the voluntary free-text option commented about whom they regarded to be responsible for MR safety incidents: personnel from departments other than radiology (44 incidents), personnel from radiology (13 incidents), or a patient or relative (16 incidents); for 24 incidents the responsible party was unspecified.

Assessment of severity of human injuries based on free-text descriptions gave severity scores of 1 to 3 for MR and 1 to 4 for CT, where the case with score 4 in CT refers to an anaphylactic reaction to contrast media with fatal outcome. In the MR cases, potential—worst-case scenario—severity scores were higher than actual severity scores for human injuries, while unchanged for CT. Among all MR incidents, 16% were given the highest potential severity score. The items involved in the MR incidents and the severity scores are given in Table 8.

Table 8.
Numbers of MR safety incidents (n), which were further specified by participants in voluntary free-text comments, grouped according to cause and evaluated regarding severity score (SS) for actual human injuries and potential severity score (PSS) based on worst-case scenarios for all safety incidents. Severity scores: 1 = minor (discomfort or insignificant injury), 2 = intermediate (transient sensory, motor, physiological, intellectual, or mental disability; extended care episode; or increased care level), 3 = significant (persistent moderate sensory, motor, physiological, intellectual, or mental impairment; extended care episode; or increased care level), 4 = catastrophic outcome (death or persistent major sensory, motor, physiological, intellectual, or mental disability).

Incident	Human injury			Material damage		Close call	
	n	SS	PSS	n	PSS	n	PSS
Burns (total)	5[a]	2	3	0	-	0	-
Projectile (total)	3	1–2	3	19	2–4	57	2–4
Small, blunt	*0*			*3*[b]	*2*	*15*[c]	*2*
Small sharp/median size	*3*[d]	*1-2*	*3*	*15*[e]	*3*	*31*[f]	*3*
Large/heavy metal	*0*			*1*[g]	*4*	*11*[h]	*4*
Implant (total)	0	-	-	0	-	8	2–4
Pacemaker						*3*	*4*
Splinter close to eye						*1*	*3*
Other						*4*[i]	*2*
Ergonomics (total)	3[j]	1	2	2[k]	2	0	-
Total n/max. score	11	2	3	21	4	65	4

Short explanations of objects/actions involved, with number of incidents given in parenthesis (n): a, skin-skin contact or loop (1), skin-coil contact (3), unspecified (1); b, glasses (1), hair clip (1), equipment part (1); c, hair pin (1), screw (1), keys (3), basket lid (1), phone (3), unspecified metal object in pocket (6); d, unspecified sharp object (1), unspecified magnetic object (1); wheelchair (1); e, scissors or knife (2), crunches (1), wheelchair (3), walker (2), ventilator/monitor (3), infusion pump (2), vacuum cleaner (1), cart (1); f, scissors or knife (7), crunches (2), laryngoscope (2), forceps (2), wheelchair (4), rescue stretcher (1), walker (6), ventilator/monitor (1), infusion pump (4), cleaning cart (1), cart (1); g, oxygen tank (1); h, oxygen tank (5), bed (6); i, leg prosthesis (1), tracheal tube (1), undefined metal implant (2); j, heavy lift/bumping into equipment (3); k, squeeze from equipment during table movement (2). Table slightly modified, reprinted with permission, Hansson et al. (81)

Confidence in incident-reporting mechanisms

More MR workers than CT workers were confident that any safety incidents or close calls that might have occurred at their workplace would have come to their notice (mean for human injuries, material damage, and close calls: 73% of MR workers vs. 50% of CT workers). At hospitals with incidents reported, 82% of MR users did not report having knowledge of any incident. An average of 61% of these users do not acknowledge the possibility that incidents might have occurred without their knowledge (65% for human injury; 62% for material damage; and 57% for close calls). Thus, the proportion of MR workers who reported that they were not aware of any incidents at their workplace(s) —although other participants at their workplace had reported a safety incident— was somewhat lower (mean for human injuries, material damage, and close calls: 69%) than for CT workers (83%), shown in detail in **Table 9**.

When we only considered participants working with both modalities (n = 208), the participants were significantly more confident that any safety incident that might have occurred at their workplace concerning MR would have come to their attention than regarding any safety incidents concerning CT (McNemar's Chi-squared test with continuity correction; $p<0.0005$ for human injury, material damage and close call).

Table 9.
Numbers of participants (n; %) working with MR and/or CT who were **confident (C)** or were *not confident (NC)* that safety incidents that might have occurred at their own hospital, and involving their modality, would have come to their notice. Participants have been grouped according to whether or not they worked at hospitals with reported safety incidents and whether or not they reported incidents themselves.

Participants working at hospitals with (yes) or without (no) reported safety incidents.		**Participants who did (yes) or did not (no) report any safety incidents.**	**Participants (n) who were confident or *not confident* that safety incidents that might have occurred at their hospital would have come to their notice.**			
				Human injury	Material damage	Close call
MR	yes	yes	**confident**	**15**	**32**	**63**
			not confident	*4*	*5*	*19*
	yes	no	**confident**	**44**	**49**	**68**
			not confident	*24*	*30*	*51*
	no	no	**confident**	**208**	**181**	**101**
			not confident	*50*	*48*	*43*
CT	yes	yes	**confident**	**22**	**13**	**-[a]**
			not confident	*11*	*10*	*-[a]*
	yes	no	**confident**	**62**	**47**	**49**
			not confident	*82*	*82*	*73*
	no	no	**confident**	**121**	**102**	**112**
			not confident	*95*	*138*	*136*

a Due to a design problem in the questionnaire 14 participants, who reported a close call for CT, could not answer the question on confidence in incident-reporting mechanisms, and are thus not included in this evaluation. Table slightly modified, reprinted with permission, Hansson et al. (81)

Paper IV

Compliance with screening routines

Out of the 1819 subjects, 1789 (98%) were examined and of these, 1456 (81%) had correctly documented approval of screening step-1 to step-4 (screening steps

described previously in the background (**Figure 5**.)). Adding 21 subjects, who were not examined, in total 1477 (81%) of the 1819 subjects included, had correctly documented screening steps. For 342 subjects the documentation of screening was incomplete. Screening form (SF) 1 was missing for 22 subjects and SF2 for 12 subjects. The most common reason for incomplete documentation was missing fields (n = 478 in 307 subjects). In six subjects with incomplete documentation, abortion of the screening process was identified as reason regarding lacking documentation; none of these subjects were examined.

MR safety risks identified during the screening process

The number of affirming, negating and missing answers to screening questions in SF1 and SF2 are given in **Table 10** and **Table 11** respectively. Implants, defined as passive and active implants, devices or foreign bodies, (n = 315) were identified in SF1 and SF2 in 305 individual subjects. Surgery involving the head, brain or heart were reported by 73 subjects in SF1, while the broader question for any type of earlier surgery in SF2 yielded 873 positive answers, of which 793 (91%) were directly evaluated as not relevant from an MR safety perspective by the personnel performing the interview. Of the 80 subject's with surgeries documented as relevant in SF2, 59 had information not covered by SF1. In 24 subjects, information regarding surgeries found in the screening process required the 7T MR safety committee to clear/not clear the subject for the imminent examination, as detailed below. Scars not related to surgeries mentioned earlier in the screening process were reported by 556 subjects, mainly covering superficial skin scars and judged as relevant in 19 subjects, however, none revealing a potential risk when evaluated further.

Tattoos were reported for 326 subjects (**Table 11**), and in 59 subjects the tattoo was located within the radiofrequency field of the used transmit/receive coil (defined as in the coil or within 30 cm from the coil boarder), but none of the tattoos was considered a contraindication.

Pregnancy (female subjects) and renal disease was documented correctly in SF1 by all but eight subjects for both questions (**Table 10**). As pregnancy was considered as contraindication for 7T MR at the facility during the study period, no pregnant subjects should be examined. Among the eight female subjects with missing documentation regarding pregnancy six were aged > 60 years, one subject did not enter the scanner room and for one subject examined documentation did not exclude pregnancy. None of the 15 subjects with renal disease or missing information regarding renal disease were given intravenous contrast media.

Items not suitable to bring into the scanner room (n = 78) were after screening step-3 found in 75 subjects (**Table 11**). Subjects themselves (n = 49) identified 52 items

and interviewing personnel identified 26 items during step-4. Jewellery, watches and piercing (n = 16) were most common among 27 specified items. Other items were medical patches (n = 3), hearing aids (n = 4), and removable dental device, glasses, bra, and hair pin (n = 1, each). Documentation on items found when passing the ferromagnetic detector was incomplete, as not included in SF2, however, one hair pin was documented. Main potential MR safety risks identified in SF2 and not in SF1 were implants not reported in SF1, but discovered in SF2 (n = 105), surgeries mentioned by patients during the interview (SF2) and judged as potentially relevant for further enquiries (n = 80), and items not suitable to bring into the scanner room identified after information to subject and change of garments (n = 78) (**Table 11**).

Table 10.
Questions in screening form 1 (SF1) and frequency of positive, negative and missing answers to individual questions. The questions printed previously in method **Table 3.**

Q	N subjects (n = 1797; SF1 missing form n = 22)		
	yes	no	missing fields
1	73	1724	0
2	203	1593	1
3	7 a	1782	8 a
4	0	916	8 b

a, none of these subjects received a contrast agent; b, six subjects with a missing field were aged > 60 y, one subject did not enter the scanner room, and for one subject entering the scanner room, pregnancy information was not documented and no reason could be identified;

Table 11.
Questions in screening form 2 (SF2) and frequency of positive, negative and missing answers to individual questions. The questions printed previously in in method **Table 3.**

Q	N subjects (n = 1807; SF2 missing form n = 12)		
	yes (relevant*) / new info. SF2	no	missing fields
1	873 (80) / 59	928	6
2	556 (19)	1240	11
3.1	43	1757	7
3.2	32 / 2	5	6
4	195 / 103 c	1571	41
5.1	1748	49	10
5.2	1633	26	148
6	326	1422	59
7	1766	14 d	27
8	24	1706	77
9	1738	na	69

c, two subjects with new items identified in SF2 Q4 were not scanned due to the new information; d, mainly parents or spouse or unspecified; na, not applicable. e, relevant, based on screening routines and training directly judged as of potential interest from an MR safety point of view.

Implants, defined as passive and active implants, devices or foreign bodies, (n=315) were identified in SF1 and SF2 in 305 individual subjects. Dental retainers (n=127) and dental implants dominated (n=69) followed by orthopaedic fixation in extremities (n=45). New information regarding implants was revealed in SF2 in 102 subjects (106 items) necessitating an ad hoc safety decision to be made by the

personnel. Two examinations were cancelled due to implants not cleared for 7T MR (one coronary stent and one metal splinter, both not further investigated as both were healthy volunteers and risk/benefit or radiation dose were not motivated).
The reasons for not performing the MR examination in 30 subjects were: technical problems not related to the subjects (n = 19), claustrophobia (n = 3), intracranial electrode (n = 1), foreign object in eye (healthy volunteer so radiation dose from a CT scan to identify the object was not motivated) (n = 1), cardiac surgery unclear stent and no further investigation due to healthy volunteer (n = 1). Other reasons were; subject decline participation after arrival to site (n = 1), impossible to put subject in supine position (n = 1) subject does not feel well (n = 1), massive hair extension not fitting into coil (n = 1), and test of acceptability of bore in one subject with pre-examination anxiety (n = 1).

Documentation of actions necessary prior to MR examination based on information provided by the interviewer in SF2 was scarce (n = 24) considering the number of implants identified and the decisions the 7T MR safety committee made. While actions were not further specified in 11 subjects, actions listed were: discussion with physicist (n = 2), with radiologist and surgeon (n = 2), referral to 7T MR safety committee (n = 3), no examination (n = 3), extra check and discussion regarding tattoo within radiofrequency field (n = 1), medical patch removed (n = 1) and the need to cut necklace (n = 1).

MR safety committee documentation

For 36 of the 1819 subjects, the 7T MR safety committee documented a decision regarding implants or surgeries identified during the screening process. Out of these evaluated cases, three were not MR examined. However, they were not examined due to: claustrophobia in a patient with a small fragment in a finger; test of acceptability of bore in one subject with pre-examination anxiety, and with an orthopaedic fixation in a toe; chest pain prior to examination in one case with an arterial pressure device and a spine fixation. Notably the arterial pressure device was not documented in the screening forms, although evaluated by the 7T MR safety committee. From the MR safety committee documentation it can further be deducted that in the scheduling process, step-1 of the safety screening, the 7T MR safety committee denied examination of five subjects and, thus, none of these five subjects were scheduled and are therefore not included in the study population of 1819 subjects.

Discussion

Overview

From the studies included in this thesis we have learned that subjects undergoing an MR examination feel that their health can be affected by UHF MR, but the discomfort is well tolerated and does in general not prevent them from going through more investigations in the future. The experience of an MR examination can be improved by personnel focusing on reducing anxiety and optimizing information and communication. Health effects, however, do not only relate to those subjectively experienced but also include safety incidents that could potentially result in human injury. Safety incidents including human injury and material damage, as well as close calls do occur at all MR sites and are potentially dangerous. To acknowledge potential risks, to reflect on feedback mechanisms, and to optimize screening procedures is essential for personnel working at MR sites to prevent MR safety incidents.

Short-term effects and compliance with UHF MR

Compliance of 7T MR examinations in an actively shielded 7T MR was shown high in paper I and II, although the study participants experienced a high frequency of short-term effects related to the examination. Most short-term effects that occurred during the movement of the subject into the scanner bore were less prevalent in paper II compared to paper I. The decrease in frequency of some of the short-term effects might partly be related to the change from using a VAS scale (with a slide bar) in the questionnaire to the use of six- or seven-step scales, avoiding positioning of the slide bar at very low numbers instead of an anticipated zero. However, the numbers are still high in comparison to other publications (12, 14, 15). In Heilmaier et al. 60%, and in Theysohn et al. 46% of the subjects reported dizziness during movement into or out of the magnet (12, 14). Considering other studies performed on the use of passively shielded magnets, another explanation might be the adaptation theory – related to differences in the short-term effects of passively and actively shielded 7T systems – based on biological mechanisms, including

adaptation to a continuous vestibular stimulation. The vicinity of the passively shielded system, and therefore the area in which the subjects are prepared on the table before entering the bore, has a higher stray field than the surroundings of the actively shielded system (used in our studies), thus the subjects have less time to adapt to a higher field before going into the scanner described in paper I than before going into scanners used in other publications (82, 83). Direct comparison between AS an PS magnets is difficult, as large patient groups are required and scanners often differ regarding not only shield coils and resulting fringe fields, but also other aspects, for example gradient coil design which might influence the occurrence of peripheral nerve stimulation (PNS) (2, 42, 84). We therefore advocate exploration of further large scale populations from different types of actively shielded ultra-high field systems.

In paper I we did not see only one explanation for the high occurrence of PNS in our material. We believe that a systematic difference compared to other systems is possible, regarding the geometry of the gradient coil, or a systematic difference in the estimation of dB/dt in relation to the limits in the IEC-standard. As Winkler et al. (5) suggest; the high occurrence of PNS at 7T scanners might be the high level of dB/dt for protocols used in research studies. However, as data on dB/dt are sparse for other studies this can only be assumed.

From comments made by study participants who were part of paper I, it became clear that the experience and/or strength of twitching could affect the degree of discomfort experienced by individual study participants very differently. Some individuals might experience single mild twitches as being very uncomfortable while other study participants might experience even several severe twitches as being absolutely acceptable, and not relate the experience to discomfort. When ultra-high field is used clinically, it is essential to minimize any undesired effects and optimize compliance. To further investigate whether predicted PNS values may be considered important for comfort/discomfort experienced in UHF MR examinations, paper II addressed all three parameters of PNS experience: quantity, intensity, and discomfort. A majority of the subjects who experience PNS did report it as being “not uncomfortable at all” or “very little uncomfortable”. This was in line with an overall high level of acceptance for ultra-high field examinations both for patients and healthy volunteers both in our and other studies (12, 14, 15, 85, 86). In further dedicated studies, it would be of interest to collect more precise information on anatomical position of PNS in subjects and correlate them to body stature and field profiles of the gradient coil and compare findings to simulations, such as proposed by Davids et al. (84). Such studies might also further focus on individual differences in perception of PNS regarding quantity and intensity of twitches under comparable conditions. The proportion of subjects who reported PNS in paper II was higher than in earlier publications (13, 14) ranging from 13 to 44 %, but was very similar to paper I (63% and 67%, respectively), without any apparent effect of

the change from VAS to step scales. As mentioned above the design (and especially the length) of the gradient coil has significance for PNS, as a longer gradient coil covers more of the body surface. Glover (2009) (42) carefully studied the causes and risks of PNS and concluded that although the threshold limits for nerve stimulation are well known, there still are difficulties in applying them to a specific system and subject geometry. Our findings in paper II also indicate that the experience of PNS may be more dependent on the individual undergoing the scan than the predicted PNS value and the level of dB/dt to which the subject is exposed. Compared to paper I, the subjects were informed before the examination that PNS might occur in the study of paper II, but they were not always pre-warned about upcoming sequences when the system warning for high predicted PNS occurred. Subject feedback in the study of paper I indicated a preference for being prepared prior to sequences with high predicted PNS. In paper II 1.5% of the subjects who experienced PNS, rated the experience as "very uncomfortable" or, "very much uncomfortable", but most of the subjects who experienced PNS rated the experience as "not uncomfortable at all" or "very little uncomfortable".

An explanation of the uncomfortable increase in body temperature experienced in a particular part of the body during the examination in paper I and II could be traced to a specific research protocol where several long fMRI EPI scans were included, and to proximity to hardware that might undergo heating during scanning, such as the inner wall of the bore. Variation in temperature in the scanner room (17-22°C) has been an issue and unfortunately, it was out of our control, although it would have been convenient to be able to adjust the scanner room temperature as appropriate. We tried to compensate for low temperature by offering the subjects a blanket.

Regarding compliance and nursing care issues, paper II revealed that data on experience of short term effects may differ between healthy volunteers and patients and that a large proportion of subjects – especially patients – stated that they had some degree of anxiety prior to the examination, and some had information- and communication-related complaints, leaving room for improvement in patient care (concerning handling and information) if we are to increase patient compliance in Ultra-High field examinations. The importance of patient care and patient compliance has also been shown by others (44, 45) focusing on patient welfare as well as throughput and image quality.

The noise generated primarily by the gradient system is a well-known issue in MR (2). The degree of acceptance of noise levels has improved, from 74% in paper I to 90% in paper II. This might be a result of improved skills in using hearing protection. None of the study subjects terminated the examination because of acoustic noise. However, improvements can still be made considering nursing efforts regarding hearing protection, as pointed out by study subjects (in paper II) in

the free text comments, and also by vendors hopefully providing improved hearing protection or noise-cancelling headphones with a built-in communication system. This would not only allow improved communication and subject entertainment, but also improve prerequisites for many fMRI experiments, suffering from confounding acoustic noise (87).

Worth noting is that 412 (43%) of the subjects in paper II showed some level of anxiety before the examination, and that patients were significantly more anxious than healthy volunteers. No significant difference in anxiety levels were observed between the first and second MR examination in subjects undergoing two examinations in the study period, which speaks against a bias due to multiple examinations. Other studies confirm the high anxiety level prior to MR examinations at 30-40% (44, 45). The main stressor in Lo Re et al. (44) was the uncertainty of the diagnosis, therapy and prognosis. Lo Re et al. (44) and Harris et al. (45) also emphasize the importance of professionalism of the radiological personnel when they receive and inform the patient, and also during the examination with emotive involvement and targeted education. This has implications of both patient welfare and image quality (44, 45).

Improved information about the examination might reduce pre-examination anxiety. To ease anxiety during the examination, some subjects in paper II have made suggestions regarding the need for more information during the examination, e.g. when they are allowed to move, the duration of the next scan, and notification before a high PNS risk sequence starts or acoustic noise levels. The majority of subjects experienced the examination as comfortable and considered the prospect of a further 7T MR examination both as patient or research subject with a positive attitude. However, Heilmaier et al. (12) described 7T examination as potentially more uncomfortable than 1.5T examination (12). The findings in both paper I and II point towards a generally positive attitude towards 7T examinations and high patient comfort also seen by others (11, 13-15), but also show that there absolutely is room for improvement when 7T MR now is introduced into clinical use (85).

MR safety

The national survey in paper III was performed to gain a baseline overview of MR safety incidents that occurred in Sweden over a 12-month period. With a response rate at approximately 60% of all MR workers in Sweden, covering 90% of hospitals/facilities with MR units in Sweden, the 21 human injuries, 50 cases of material damage, and 129 close calls reported should cover the majority of MR safety incidents that occurred during the study period. At hospitals with incidents reported, 82% of MR users did not report having knowledge of any incident. An

average of 61% of these users do not acknowledge the possibility that incidents might have occurred without their knowledge (65% for human injury; 62% for material damage; and 57% for close calls). This finding suggests that the healthcare system lacks functioning local incident report systems assuring feedback to employees. This is also reflected by the rather low percentage of multiple reporting of specified incidents. Further, radiographers working with both MR and CT had significantly higher confidence in safety feedback regarding MR than CT incidents ($p < 0.0005$), illustrating that the efficacy of feedback mechanisms at a department may differ for modalities or be perceived differently. A Danish study showed that even if the country has a national reporting system, under-reporting might occur. The main reason for not reporting incidents was lack of time, as stated by 85% of participants in the study by Blankholm and Hansson (88).

Reported MR incidents were mainly related to projectiles and burns, and were thereby related to the static magnetic field, or the radio-frequency field. Safety incidents related to ergonomic risks affected both patients and personnel and were mainly raised by CT users, which might be related to the larger throughput of patients at CT compared to MR. Reported close calls were predominant among MR safety incidents in this study, and we interpret this finding as reflecting a considerable awareness of safety risks in MR and that safety practices and routines are in place as a necessary base for MR accident prevention. No lethal cases were reported for MR in this study. However, as a high number of close calls have been reported involving large items such as wheelchairs, ventilators, oxygen tanks, and beds, several lethal cases could have happened, inciting again on the necessity to adopt international recommendations for safety (55, 58, 67, 89-91). The safety guidelines comprise for example; education recommendations on various personnel categories; MR screening procedures and screening forms; site planning and zone divisions; and final check before entering the MR scanner room. The necessity to adopt international recommendations was also reflected in the fact that 15 (16%) MR safety incidents specified were given the highest potential—worst case scenario—severity score.

MR related risks are manifold, incident prevention is complex and relies heavily on employees and thus patients become vulnerable in MR environments (88). Factors to minimize this vulnerability are continuously reviewed safety routines, education of personnel, feedback mechanisms on incidents and the much more numerous close calls, and a change of culture towards learning from mistakes (47, 49, 51, 66, 92-94, 95). Further, confidence in internal communication or local reporting systems might be much greater than the true usefulness of such routines, as shown in this study, and they need to be designed carefully (51). Jones et al. (51) describes a well functioned reporting system to be based on an underlying information model as with those in other high-risk industries, such as aviation, railroads, oil drilling, and nuclear power (51). Even if most MR sites in Sweden have safety screening forms,

advocated as single most effective measure for prevention (95), MR safety incidents still occur. Radiographers, radiologists, personnel from other departments accompanying patients to MR units, administrative personnel, janitors, and firemen are important pieces of the MR safety puzzle, and leaving out one piece might jeopardise security and possibly lead to a catastrophe (55). Personnel not working regularly with MR is considered by 61% of the participants in the study of Blankholm and Hansson (88) to be a high risk factor for incidents (88).

Based on the results in paper III, severe adverse events still exist, are poorly shared within the team, and are preventable. Thus, the following action steps are mandatory: 1/ identify potential risk zones; 2/ design specific educational programs dedicated to every category of professionals who work in or might visit MR sites; 3/ state clear MR safety procedures including screening forms that are confirmed with an interview just before entering the MR scanner room; and 4/ facilitate rigorous but easily manageable incident reporting systems with focus on prevention and learning from mistakes. Our recommendations are in line with the national recommendations of the American College of Radiology and the Medicines and Healthcare Products Regulatory Agency UK, where education, screening procedures and risk zones are highlighted (76, 91).

MR safety screening is a complex process involving the patient, referring entity and a multi-professional team at the MR site. Given the results in paper IV, the multi-step screening process showed inadequacies in compliance but also benefits of repetition and a documented structured screening interview.

MR safety incidents are a result of failure by health professionals to comply with standards or rules, or the absence of such regulations to follow. The compliance with safety routines is essential not to normalize the deviance (94, 96). Paper IV revealed that documentation of the screening process was not complete in 19% of the subjects. This might simply reflect a difficulty of uniform documentation or worse, inadequate nursing care. Kalisch and Faan (77) pointed out implications for compliance in nursing care, addressing the necessity of personnel being engaged in both collection and analysis of such data, but also the importance to create a culture of quality and safety that ensures attention to detail and honest reporting (77). According to ACR's recently updated recommendations, MR personnel should not work alone when working with human subjects, and all workers should have adequate MR safety education (76). Teamwork is important not only for emergency safety issues, but also for consultation, to avoid breaches of risk defense mechanisms and to learn from mistakes and improve risk reduction strategies (97). Lack of documentation, in some cases might reflect insecurity or avoidance of transparency. However, for trained personnel, failure to comply with routines does normally not represent an intention to harm, but often represents barriers to use correct processes, such as time, cost and pressure (94).

The multi-step screening procedure facilitated detection of additional MR safety risks in later steps although already asked for in earlier steps. The benefits of repeating similar and wider questions in SF2 were detection of implants and foreign bodies and detection of various types of surgery that might have resulted in an implant. While 7T MR is becoming a clinical tool (23, 85), the community still lacks an exchange of results of MR safety tests from 7T facilities (98) and there are only a few publications reporting implant testing in 7T environment (73, 74). Although our study population likely consisted of healthier and younger subjects compared to full time clinical scanners, numbers of implants and foreign bodies were still higher compared to a previous 7T publication (19). While 7T is becoming a clinical tool, individual risk benefit assessment becomes more important. Refusal of MR examinations can have a large impact on patient care and treatment decisions (71). Even to allow a rather young and healthy population, such as the one presented in this study, to undergo ultra-high field MR demands that conservative exclusion criteria – such as not scanning any implants – have to be revised and that an individual oriented risk assessment has to be applied, an opinion that has also been expressed by others (19). However, this assumes that personnel performing the screening has the adequate training for decision-making and access to some form of MR safety committee for more challenging cases (55, 76). Considering that our study population of 1819 subjects reported more than 300 implants, close to 900 previous surgeries and more than 300 tattoos, decision making is a challenging duty, especially as only very few subjects actually could not be scanned due to these potential contraindications. The latter might also indicate, that the referral and booking process, step-1, in the multi-step screening process was efficient and that documented decisions of the MR safety committee facilitated decision making.

Changing into MR approved garments and instructing subjects to remove items not suitable to be brought inside the magnet room, as also suggested in the American college of radiology (ACR) Manual on MR Safety (76), is essential. Additionally, to then check compliance with this information showed to be effective in our population and can be complemented with a ferromagnetic detector as an additional MR safety tool. The utility of a ferromagnetic detector as an additional MR safety tool is confirmed by the study of Weidman et al. (70) that takes the detector even further connecting it to the light in the scanner room (70). Changing into MR approved garments also further decreases the risk of introducing safety risks to the MR environment by means of garments including not suitable metal threads, components treated with antimicrobial electrically conductive materials, prints or accessories (76). A strict clothing policy might prevent accidents as the tragic incident with a radiographer wearing a weight vest, described by Philip Ward in AuntMinnieEurope.com (99), last year at Sunderby hospital in Luleå, Sweden.

Methodology and limitations

Differences in occurrence and strength of experienced short-term effects reported in the literature rise the question of possible biases influencing study results and comparability. Some of the differences observed between studies on short-term effects might be explained by their use of different scales and questionnaires, and different ways of presentation of the results as well as further bias factors. In paper I we struggled with comparing the findings from publications with very different approaches to present results (11-15, 31).

Information regarding expected short-term effects given to study subjects prior to the examinations performed, is not sufficiently detailed in all publications and may span from unstandardized minimal information to exact information on which short-term effects should be reported at a specific time point of the examination or experiment. The amount of information given in paper I was designed to balance the aim of keeping information bias as low as possible with requirements from the ethical board and patient care, the latter aiming at high compliance and patient comfort. Over-reporting of short-term effects as consequence of information bias can of course not be excluded, neither for our study nor any other study.

Besides information, other aspects evaluated in paper I and II might be influenced by handling the subjects by the personnel and thus the diversity of personnel – researchers, radiographers, MR physicists, radiologists, and physicians. We tried to minimize this potential bias as all personnel at the facility receives training from a limited number of radiographers, who work closely together and supervise or perform a majority of the scans. Examples of other aspects that might be influenced by the diversity of personnel are application of hearing protection and communication skills, potentially influencing experience of noise, and communication.

Recognition bias in paper I and II might be a potential drawback for individuals who have undergone several examinations either on scanners with other field strengths or repetitive scans at the 7T. However, this is also true for larger studies in the literature, usually not excluding subjects with several scans or earlier MR experience (13). These subjects might further experience various examinations differently e.g. regarding PNS depending on the used sequences or body part examined, but also due to adaptation bias, a factor reported by several subjects but not within the scope of paper I or II. It can also be argued whether recognition or expectation bias might potentially influence compliance with screening procedures in paper IV, as personnel may know the study subject to be screened personally or the study subject might have been examined at the facility several times earlier.

Expectation bias was not analysed in paper I, but might not only be of importance regarding given information but also considering the way individuals will approach an MR examination. The expectation of a patient undergoing a clinical MR scan will primarily focus on the test result (44), while healthy volunteers in research examinations, not least at ultra-high field facilities, might in general focus on the experience itself, possibly leading to higher reported frequencies of short-term effects independent of prior knowledge. In paper II we addressed this problem and the result showed that the difference between patients and healthy volunteers, in reporting effects was mostly seen in anxiety, with the patients reporting more anxiety than the healthy volunteers prior to the examination.

In both paper I and II we did not have a control group or control situation with examinations performed at another field strength, a passively shielded scanner with otherwise comparable technical specifications or a mock scanner. This is a limitation that we could not overcome considering the large number of subjects included in the study and the design of the study focusing on inclusion of all subjects examined at a certain scanner independent of status as healthy volunteer or patient, of indication of the study, or of examined body part. Considering the number of subjects, the variety of study protocols and the fact that subjects were included after performance of a 7T MR examination performed for other reasons than this study, it was not possible to measure vital signs or neurocognitive functions.

In paper III, the nationwide survey well represents the MR environment in the country and was also internationally generalizable regarding many aspects in terms of reported incidents (46, 62). However, a survey of this kind can never claim to have complete coverage, and always leaves room for selection bias. Both underestimation and duplicate recording may have occurred. Incidents involving large and more hazardous objects might be more frequently reported than incidents with smaller and less hazardous objects (81).

From an ethical point of view and to protect the integrity of employees, answers in paper III were completely anonymous and data are presented avoiding identification of specific facilities and their association with particular incidents. This limited the possibility of double-checking incidents, although similar descriptions of incidents in the free text comments, concerning incidents occurring at the same hospital, have been detected and led to exclusion of multiple reporting. However, to encourage participants not to hold back due to fear of individual identification, the free-text comment for specification of incidents was optional.

Our assessment of severity scores in paper III, based on adapted national recommendations, can of course not be compared to a full-scale risk assessment based on detailed data concerning a specific incident. However, putting the reported and specified incidents into a severity context is of great importance, to highlight possible future risks and to MR safety-prevention work.

In paper III we chose to use CT for comparison, as there are many similarities between the two work environments. Limitations of this approach were, for example, the significantly higher proportion of full-time working hours dedicated to the modality of MR, compared to CT, and the known difference in throughput of examinations per hour for the two modalities.

A limitation of paper IV is that the study was performed at a 7T MR site, as fewer subjects might be expected to have implants and the population to be younger compared to clinical scanners. However, as fewer implants are labelled for 7T than for lower fields, we judged a comparison between the short SF1 and the comprehensive SF2 to be most advantageous to be performed in a setting with potentially high awareness of MR safety risks and well defined training of personnel. Further, the design of SF2 does not completely match today's recommendation standards (56, 76); however, it was a condensate of and compromise between recommended extensive questionnaires and questionnaires used at 7T sites at the time. A further limitation of this study was the omitted documentation regarding objects found with the ferromagnetic detector.

Clinical impact

The number of clinical MR examinations is constantly increasing in health care (3), resulting in an increase in MR safety risks. Therefore, adequate risk assessment and nursing care before and during the examination are of paramount importance, as well as the work environment for the personnel. The four papers included in this thesis identify potential health effects and risk factors for patients and personnel and indicate care and safety routines that can be applied directly. MR safety deficiencies can lead to catastrophic outcome for both patients and personnel. This thesis has high relevance from a broad public health and healthcare perspective, highlighting MR safety and health issues from the perspective of both patients and personnel. This thesis has generated results and conclusions that can be applied to a wide patient population, as well as healthy volunteers in research environments, and improve the working environment for MR personnel.

Conclusion

In conclusion, this thesis overall contributes to an increased understanding of the importance of MR safety work and the origin and prevention of MR health effects.

The following conclusions can be drawn from the individual papers in this thesis:

Paper I

Dizziness, inconsistent movement, and PNS are the most frequently reported short-term effects in paper I, and the results indicate that experience of short-term effects may differ between actively and passively shielded 7T MR scanners, although these differences need not only be related to the shielding of the system, but also other aspects of system design or study design differences. Patient comfort was generally experienced as high, but areas for improvement were identified regarding nursing care strategies, such as supplying better information and paying attention to the needs and the comfort of the individual at all times.

Paper II

In paper II, health effects experienced in actively shielded ultra-high field MR include physiological responses and also highly individual psychological issues. However, few subjects experience these effects, although frequent or intense, as being so uncomfortable that they would be reluctant to undergo possible ultra-high field MR examinations in the future. Considering the data, compliance and experience might be further improved by focusing on pre-examination anxiety, communication, and supplying information before and during the examination in parallel to technical advances decreasing the physiological impact.

Paper III

Paper III has shown that safety incidents resulting in human injury, material damage, and close calls in clinical MR environments do occur. Risk levels of these incidents are high. Results indicated that MR personnel tend to have a false sense of security, as a high proportion of personnel were sure that they would have been aware of any incident occurring in their own department, while in reality, incidents did occur without their knowledge. Using CT for comparison highlighted that individuals might consider safety and feedback differently, depending on the modality in question.

Paper IV

Based on results of paper IV, MR safety screening is a complex process involving the patient, referring entity, and a multi-professional team at the MR site, handling a large number and variety of MR safety decisions. To allow a transparent screening process, compliance with the screening is mandatory, and this can only be assessed if documented. A multi-step screening process and its evaluation showed inadequacies in compliance. However, it also offered benefits through repetition and the use of a documented structured screening interview and as a result additional potential MR safety risks were identified.

Future research

My research has formed rings on the water, and my future research will hopefully bring more knowledge into the field of MR health effects and MR safety. The future research will involve interesting collaborations with other researchers and my hope is to be able to guide and inspirer others.

In a collaboration with researchers from Karolinska Institute, Stockholm, we will analyse unique data on subject's habituation to strong magnetic fields regarding health effects. Subjects participating in a functional MR study evaluating motor skill at several points with 7T MR, have answered an adapted experience questionnaire (papers I and II) after every 7T MR examination. Data collection has recently been concluded, and data analysis is planned for this autumn.

Based on our previous work on 7T MR health effects (paper I and II) we will further investigate anxiety prior to MR examinations in collaboration with researchers at Clinical Sciences Lund, Lund University.

Together with my main supervisor we continue a collaboration with the department of neurology, Lund University, on epilepsy patients examined at 7T. This study benefits from the knowledge obtained in papers I and II on patient care in the 7T MR environment and yields interesting insights into prerequisites needed for examinations performed in patients with complex disease histories including previous brain surgery, the risk of seizures during examinations and a potentially high level of anxiety.

Data collected in the national questionnaire for paper III included not only data on MR safety presented in paper III, but comprised also aspects on working environment, self-estimated health and potential effects of MR on hearing. The continuation of this study aims to delineate physical and biological factors affecting the large group of personnel working in the MR environment near strong magnetic fields, including psychological, social and noise related factors. Gained knowledge might be used for the design of adapted work environments that prevent negative health effects and promote the health and safety of the individual. The continued study is conducted in close collaboration with, Umeå University. Researchers at Umeå University have a long experience of research on human exposure to risks in work environment.

Further, paper III has inspired other colleagues interested in MR safety to explore safety knowledge and issues at MR units in Sweden. A collaboration with the University of Linköping on MR safety incidents is ongoing.

The MR safety work in paper III and IV might lead to implementations in the development of national MR safety guidelines based on a close collaboration with the MR safety responsible radiographer at Skåne University Hospital and members of a national MR safety group working on guidelines.

Sammanfattning på svenska

För att undersöka människokroppen på insidan används idag ofta magnetresonans, förkortat MR. Med denna avancerade teknik kan man med hög precision bland annat ta reda på sjukdomstillstånd, skador, hur hjärnan, andra organ och metabolismen fungerar. Det är såklart oerhört värdefullt inom vården och forskningen. Men för att MR-kamerorna ska fungera krävs att de undersökta personerna utsätts för starka magnetfält – och hur detta påverkar människor har inte varit helt klarlagt. Dessutom behöver man vara säkerhetsmedveten i samband med undersökningarna. Denna avhandling innehåller fyra djupgående studier som kan vägleda och bidra till ökad säkerhet för det framtida användandet av MR-tekniken inom vård och forskning.

Magnetresonans (MR) är en fantastisk kombination av avancerad vetenskap och teknik, som ofta finns på röntgenavdelningen på ditt lokala sjukhus. Det är en metod baserad på känslighet för vatten vilket passar bra för människokroppen som till 60 procent är just vatten. Egenskaperna och mängden vatten i olika vävnader kan förändras dramatiskt med sjukdom och skada, vilket gör MR till ett känsligt diagnostiskt verktyg. MR kan avbilda anatomi och patologi, men undersöker också organfunktion och visualiserar metabolism (MR-spektroskopi) och hjärnfunktion (funktionell MRI). Det statiska magnetfältet för en vanlig MR-kamera idag är 1,5 eller 3Tesla (T). Detta magnetfält är 30 000 till 60 000 gånger starkare än jordens magnetfält vid jordytan – eller ungefär 300 till 600 gånger starkare än en kylskåpsmagnet. Magnetfältet är alltid på eftersom du inte stänger av en MR-kamera om den inte är trasig eller om det hänt en olycka.

Mångsidigheten och flexibiliteten hos MR har lett till en mycket stor efterfrågan på MR-kameror, vilket har fått till följd att antalet kameror ökat dramatiskt under de senaste tre decennierna, och fler patienter och personal exponeras för dem. Utvecklingen går även mot högre fältstyrka, upp till 7T. Huvudorsaken för teknikutvecklingen av MR vid ultrahöga fält (UHF över 4T) är ökningen av signal-till-brusförhållande vilket leder till bilder av högre kvalitet och ger möjlighet att få ny insikt om sjukdomar och människokroppens funktion. När ultrahögfälts MR-kameror nu går från forskning till klinisk användning är det viktigt att undersöka möjliga samband mellan exponering för starka magnetfält och hälsoeffekter. Det

kan vara nödvändigt att se över rutiner. Även om studiepersoner har visat sig tolerera ultrahöga fältstyrkor väl, har de rapporterat korttidseffekter som yrsel, inkonsekvent rörelse (banan-känsla), illamående och metallisk smak. I allmänhet finns det en positiv inställning till 7T-MR-undersökningar. Trots detta finns det absolut utrymme för förbättringar när det gäller omvårdnad, speciellt nu när 7T MR förflyttas från enbart forskning till klinisk användning.

I **första delstudien** var syftet att utvärdera korttidseffekter, som upplevdes av studiepersoner i en aktivt skärmad 7T MR. Dessutom var syftet att diskutera skillnader jämfört med resultat i litteraturen från passivt skärmade 7T-kameror, och för att beskriva möjliga sjukvårdsstrategier som kan förbättra patientens upplevelse.

Den **andra delstudien** var en fortsättning av den första delstudien. Syftet var nu att undersöka mängden, intensiteten av och subjektivt beskriva upplevelser från effekterna av 7T MR. Detta gjordes i en storskalig studie med fokus på patientkomfort och omvårdnad. Delstudie I och II visade att kortvariga effekter såsom yrsel, inkonsekvent rörelse, illamående, huvudvärk och metallisk smak förekommer i ultrahögfält-MR, men även individuella psykologiska problem som ångest. Jämfört med litteraturen visar delstudie I och II högre frekvens av korttidseffekter jämfört med äldre ultrahögfältssystem med passivt skärmade magneter. Viljan att genomgå en framtida 7T-MR-undersökning var dock hög.

I den **tredje delstudien** var målet att kartlägga MR-säkerhetsincidenter som inträffat under en tolvmånadersperiod. Det gällde att bedöma incidenternas svårighetsgrader och utvärdera MR-personalens förtroende för rapporteringen av incidenter. Samt att jämföra med datortomografi-personal som kontrollgrupp. Det visade sig att säkerhetsincidenter i kliniska MR-miljöer inträffar och risknivån för dessa incidenter är hög. Resultaten indikerade dessutom att MR-personal tenderar att ha en falsk känsla av säkerhet, – en hög andel av personalen var säkra på att de kände till de incidenter som inträffat på deras avdelning – men i själva verket hade incidenter förekommit som de inte visste om.

Syftet med den **fjärde delstudien** var att analysera och utvärdera en dokumenterad muntlig intervju kring att öka MR-säkerheten. Delstudie fyra visade på fördelarna med en flerstegs MR-säkerhetsprocedur, men där både MR-säkerhetsrisker och brister i följsamhet av rutiner påvisades.

Sammanfattningsvis, vad kom fram i de fyra studierna kring MR:s påverkan på människor och hur man kan förbättra säkerhetsarbetet vid MR-undersökningar?

Människor upplever att deras hälsa kan påverkas vid MR-undersökningar. Men obehaget är inte så stort – det hindrar dem inte att vilja genomgå fler undersökningar i framtiden. Dessutom kan undersökningsupplevelsen förbättras genom att

personalen bland annat fokuserar på att minska ångest och att informera och kommunicera än mer med patienterna.

Det framkom också att det förekommer säkerhetsincidenter i kliniska MR-miljöer och att de potentiellt är väldigt farliga. Utöver detta fanns det en tro att man som personal kände till vilka incidenter som inträffat, vilket man egentligen inte gjorde. Men det finns sätt att jobba för att förbättra säkerheten. Genom att använda sig av en MR-säkerhetsprocedur i flera steg – med upprepade frågor och en dokumenterad strukturerad screeningintervju – kan man minska risker i det löpande MR-arbetet.

Acknowledgements

My time as a PhD student has been an inspiring and a pleasurable experience. The work with my dissertation has given me the opportunity to work with many people and I want to express my sincere gratitude.

First, I want to thank my main supervisor, Isabella Björkman-Burtscher, for everything you taught me, for encouraging me, and for being there whenever I needed your help. It has been a joy working with you. I want to thank my co-supervisor, Johan Olsrud, for the insights in the physical conditions the magnetic field has on humans. Thank you for your unobtrusive manner of moving this project forward.

Next, I want to send a thankful thought to Peter Höglund, our co-author, who very sadly passed away. He was an invaluable guide in the world of statistics and ethics.

Furthermore, I would like to thank my co-authors; Karin Markenroth Bloch, Markus Nilsson, Jonna Wilén, Titti Owman, Jimmy Lätt, Matea Simic, Pia Sundgren, Johan Olsrud, and Isabella Björkman-Burtscher for their highly valued support, suggestions, and points of view.

The National 7T MR facility at Lund University BioImaging Center and Skåne University Hospital played a central role in the development of this thesis. Thank you, Karin Markenroth Bloch, for being an excellent facility director, thank you Freddy Ståhlberg and Peter Hochbergs, for making our dream come true, thank you Pia Sundgren, for keeping it going, and thank you Mads Andersen, for always supporting us.

Thank you, to the MR Physics group under the leadership of Freddy Ståhlberg and Linda Knutsson, for letting me in, although I am not a physicist. Being a radiographer, I was an odd bird in academics, and there was no obvious research group to connect with.

I also want to thank all colleagues at the clinical department, especially Titti Owman my roommate and best cheerleader. Linda Wennberg, Helga Reesalu, and Matea Simic deserve special thanks for your support and that you had to pull a heavy load at the 7T when I was working on my thesis. Thank you, Peter Hochbergs, chair of the department, and Professor Pia Sundgren, head of the department, for making it

possible to perform research at our department, and Pia Weijdegård and Violetta Ellmer, my bosses, facilitating this thesis in many ways.

Thank you, all my friends, my mother and father, my sister and my brother, and their families, that you never stopped to encourage me and for your curiousness of what I have been working on, as well as for your patience when I explained what I have been working on.

Last but certainly not least, thank you Mikael, my husband, for believing in me and supporting me no matter what –love you–, and thanks to my children Magdalena and Magnus for your love –love you back– and because you are you.

References

1. McRobbie DW, Moore EA, Graves MJ. MRI from picture to proton. Cambridge: Cambridge University Press; 2017.
2. Panych LP, Madore B. The physics of MRI safety. J Magn Reson Imaging. 2018;47(1):28-43.
3. Gowland PA. Present and future magnetic resonance sources of exposure to static fields. Prog Biophys Mol Biol. 2005;87(2-3):175-83.
4. Shellock FG, Crues JV. MR procedures: biologic effects, safety, and patient care. Radiology. 2004;232(3):635-52.
5. Winkler SA, Schmitt F, Landes H, de Bever J, Wade T, Alejski A, et al. Gradient and shim technologies for ultra high field MRI. Neuroimage. 2018;168:59-70.
6. Moser E, Stahlberg F, Ladd ME, Trattnig S. 7-T MR--from research to clinical applications? NMR Biomed. 2012;25(5):695-716.
7. Moser E. Ultra-high-field magnetic resonance: Why and when? World J Radiol. 2010;2(1):37-40.
8. Ugurbil K. Imaging at ultrahigh magnetic fields: History, challenges, and solutions. Neuroimage. 2018;168:7-32.
9. Schenck JF. Safety of strong, static magnetic fields. J Magn Reson Imaging. 2000;12(1):2-19.
10. Chakeres DW, de Vocht F. Static magnetic field effects on human subjects related to magnetic resonance imaging systems. Prog Biophys Mol Biol. 2005;87(2-3):255-65.
11. Cosottini M, Frosini D, Biagi L, Pesaresi I, Costagli M, Tiberi G, et al. Short-term side-effects of brain MR examination at 7 T: a single-centre experience. European radiology. 2014;24(8):1923-8.
12. Heilmaier C, Theysohn JM, Maderwald S, Kraff O, Ladd ME, Ladd SC. A large-scale study on subjective perception of discomfort during 7 and 1.5 T MRI examinations. Bioelectromagnetics. 2011;32(8):610-9.
13. Rauschenberg J, Nagel AM, Ladd SC, Theysohn JM, Ladd ME, Moller HE, et al. Multicenter study of subjective acceptance during magnetic resonance imaging at 7 and 9.4 T. Invest Radiol. 2014;49(5):249-59.
14. Theysohn JM, Maderwald S, Kraff O, Moenninghoff C, Ladd ME, Ladd SC. Subjective acceptance of 7 Tesla MRI for human imaging. Magma. 2008;21(1-2):63-72.
15. Versluis MJ, Teeuwisse WM, Kan HE, van Buchem MA, Webb AG, van Osch MJ. Subject tolerance of 7 T MRI examinations. J Magn Reson Imaging. 2013;38(3):722-5.

16. Glover P. Magnetic Field-Induced Vertigo in the MRI Environment. Current Radiology Reports. 2015;3(8).
17. Hartwig V, Giovannetti G, Vanello N, Lombardi M, Landini L, Simi S. Biological effects and safety in magnetic resonance imaging: a review. Int J Environ Res Public Health. 2009;6(6):1778-98.
18. Schild HH. MRI made easy (...well almost). Berlin/Bergkamen: Schering AG; 1990.
19. Noureddine Y, Bitz AK, Ladd ME, Thurling M, Ladd SC, Schaefers G, et al. Experience with magnetic resonance imaging of human subjects with passive implants and tattoos at 7 T: a retrospective study. Magma. 2015;28(6):577-90.
20. Hawksworth D, McDougall I, Bird J, Black D. Considerations in the design of MRI magnets with reduced stray fields. T Magn. 1987;23(2):6.
21. Guidance for Industry and food and drug administration staff. Criteria for significant risk investigations of magnetic resonance diagnostic devices. 2014; Avalible via: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/criteria-significant-risk-investigations-magnetic-resonance-diagnostic-devices-guidance-industry-and.
22. Hoff MN, McKinney At, Shellock FG, Rassner U, Gilk T, Watson RE, Jr., et al. Safety Considerations of 7-T MRI in Clinical Practice. Radiology. 2019;292(3):509-18.
23. Kraff O, Quick HH. 7T: Physics, safety, and potential clinical applications. J Magn Reson Imaging. 2017;46(6):1573-89.
24. Trattnig S, Springer E, Bogner W, Hangel G, Strasser B, Dymerska B, et al. Key clinical benefits of neuroimaging at 7T. Neuroimage. 2018;168:477-89.
25. van der Kolk AG, Hendrikse J, Zwanenburg JJ, Visser F, Luijten PR. Clinical applications of 7 T MRI in the brain. Eur J Radiol. 2013;82(5):708-18.
26. WHO. Preamble to the Constitution of WHO as adopted by the International Health Conference, New York, 19 June - 22 July 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of WHO, no. 2, p. 100) and entered into force on 7 April 1948. 1946.
27. 2013/35/EU N-bgtgpfid. 2013;Avalible via: https://osha.europa.eu/legislation/guidelines/non-binding-guide-good-practice-implementing-directive-201335eu.
28. Chakeres DW, Kangarlu A, Boudoulas H, Young DC. Effect of static magnetic field exposure of up to 8 Tesla on sequential human vital sign measurements. J Magn Reson Imaging. 2003;18(3):346-52.
29. Glover PM, Cavin I, Qian W, Bowtell R, Gowland PA. Magnetic-field-induced vertigo: a theoretical and experimental investigation. Bioelectromagnetics. 2007;28(5):349-61.
30. Heinrich A, Szostek A, Meyer P, Nees F, Rauschenberg J, Grobner J, et al. Cognition and sensation in very high static magnetic fields: a randomized case-crossover study with different field strengths. Radiology. 2013;266(1):236-45.
31. Mian OS, Li Y, Antunes A, Glover PM, Day BL. On the vertigo due to static magnetic fields. PLoS One. 2013;8(10):e78748.

32. Roberts DC, Marcelli V, Gillen JS, Carey JP, Della Santina CC, Zee DS. MRI magnetic field stimulates rotational sensors of the brain. Current biology : CB. 2011;21(19):1635-40.

33. Yang M, Christoforidis G, Abduljali A, Beversdorf D. Vital signs investigation in subjects undergoing MR imaging at 8T. AJNR Am J Neuroradiol. 2006;27(4):922-8.

34. Chakeres DW, Bornstein R, Kangarlu A. Randomized comparison of cognitive function in humans at 0 and 8 Tesla. J Magn Reson Imaging. 2003;18(3):342-5.

35. Schlamann M, Voigt MA, Maderwald S, Bitz AK, Kraff O, Ladd SC, et al. Exposure to high-field MRI does not affect cognitive function. J Magn Reson Imaging. 2010;31(5):1061-6.

36. Schlamann M, Yoon MS, Maderwald S, Pietrzyk T, Bitz AK, Gerwig M, et al. Short term effects of magnetic resonance imaging on excitability of the motor cortex at 1.5T and 7T. Academic radiology. 2010;17(3):277-81.

37. Schaap K, Christopher-De Vries Y, Crozier S, De Vocht F, Kromhout H. Exposure to static and time-varying magnetic fields from working in the static magnetic stray fields of MRI scanners: a comprehensive survey in the Netherlands. Ann Occup Hyg. 2014;58(9):1094-110.

38. Schaap K, Christopher-de Vries Y, Mason CK, de Vocht F, Portengen L, Kromhout H. Occupational exposure of healthcare and research staff to static magnetic stray fields from 1.5-7 Tesla MRI scanners is associated with reporting of transient symptoms. Occup Environ Med. 2014;71(6):423-9.

39. McRobbie DW. Occupational exposure in MRI. Br J Radiol. 2012;85(1012):293-312.

40. Mian OS, Li Y, Antunes A, Glover PM, Day BL. Effect of head pitch and roll orientations on magnetically induced vertigo. J Physiol. 2016;594(4):1051-67.

41. Glover PM, Li Y, Antunes A, Mian OS, Day BL. A dynamic model of the eye nystagmus response to high magnetic fields. Physics in medicine and biology. 2014;59(3):631-45.

42. Glover PM. Interaction of MRI field gradients with the human body. Physics in medicine and biology. 2009;54(21):R99-r115.

43. Tornqvist E, Mansson A, Larsson EM, Hallstrom I. It's like being in another world--patients' lived experience of magnetic resonance imaging. Journal of clinical nursing. 2006;15(8):954-61.

44. Lo Re G, De Luca R, Muscarneri F, Dorangricchia P, Picone D, Vernuccio F, et al. Relationship between anxiety level and radiological investigation. Comparison among different diagnostic imaging exams in a prospective single-center study. La Radiologia medica. 2016;121(10):763-8.

45. Harris LM, Cumming SR, Menzies RG. Predicting anxiety in magnetic resonance imaging scans. Int J Behav Med. 2004;11(1):1-7.

46. De Wilde JP. Magnetic resonance imaging safety issues including an analysis of record incidents within UK. Progress in Nuclear Magnetic Resonance Spectroscophy. 2007(51):37-48.

47. Boutin RD, Briggs JE, Williamson MR. Injuries associated with MR imaging: survey of safety records and methods used to screen patients for metallic foreign bodies before imaging. AJR Am J Roentgenol. 1994;162(1):189-94.

48. Chen D. Boy, 6, Dies of skull injury during M.R.I. The New York Times, New York. 2001; Available via: https://www.nytimes.com/2001/07/31/nyregion/boy-6-dies-of-skull-injury-during-mri.html.

49. Expert Panel on MRS, Kanal E, Barkovich AJ, Bell C, Borgstede JP, Bradley WG, Jr, Froelich J, et al. ACR guidance document on MR safe practices: 2013. J Magn Reson Imaging. 2013;37(3):501-30.

50. Gilk T AM, Latino R. MRI Safety 10 years later. Patient Safety & Quality Healthcare, Middleton. 2011; Available via: https://www.psqh.com/analysis/mri-safety-10-years-later/.

51. Jones DN, Benveniste KA, Schultz TJ, Mandel CJ, Runciman WB. Establishing national medical imaging incident reporting systems: issues and challenges. J Am Coll Radiol. 2010;7(8):582-92.

52. Soop M, Fryksmark U, Koster M, Haglund B. The incidence of adverse events in Swedish hospitals: a retrospective medical record review study. Int J Qual Health Care. 2009;21(4):285-291.

53. Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. JAMC. 2004;170(11):1678-1686.

54. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ. 2001;322(7285):517-519.

55. Clausen L CJ, Garlock A, Perkins A, Pierce B, Seitz K, Turk J, Worthongton A, Lipman E, Odle T. Radiologic Technologist Best Practice for MR Safety. American society of Radiologic Technologists. 2018; Avalible via: https://www.asrt.org/docs/default-source/publications/whitepapers/asrt18_mrsafetywhitepaper.pdf?sfvrsn=6:

56. Shellock FG, Crues JV. MRI Bioeffects, Safety, and Patient Management: Biomedical research publishing group, Los Angeles; 2014.

57. Coskun O. Magnetic resonance imaging and safety aspects. Toxicol Ind Health. 2011;27(4):307-13.

58. Shellock FG, Spinazzi A. MRI safety update 2008: part 2, screening patients for MRI. AJR Am J Roentgenol. 2008;191(4):1140-9.

59. Silva AK, Silva EL, Egito ES, Carrico AS. Safety concerns related to magnetic field exposure. Radiation and environmental biophysics. 2006;45(4):245-52.

60. Calamante F, Faulkner WH, Jr., Ittermann B, Kanal E, Kimbrell V, Owman T, et al. MR system operator: recommended minimum requirements for performing MRI in human subjects in a research setting. J Magn Reson Imaging. 2015;41(4):899-902.

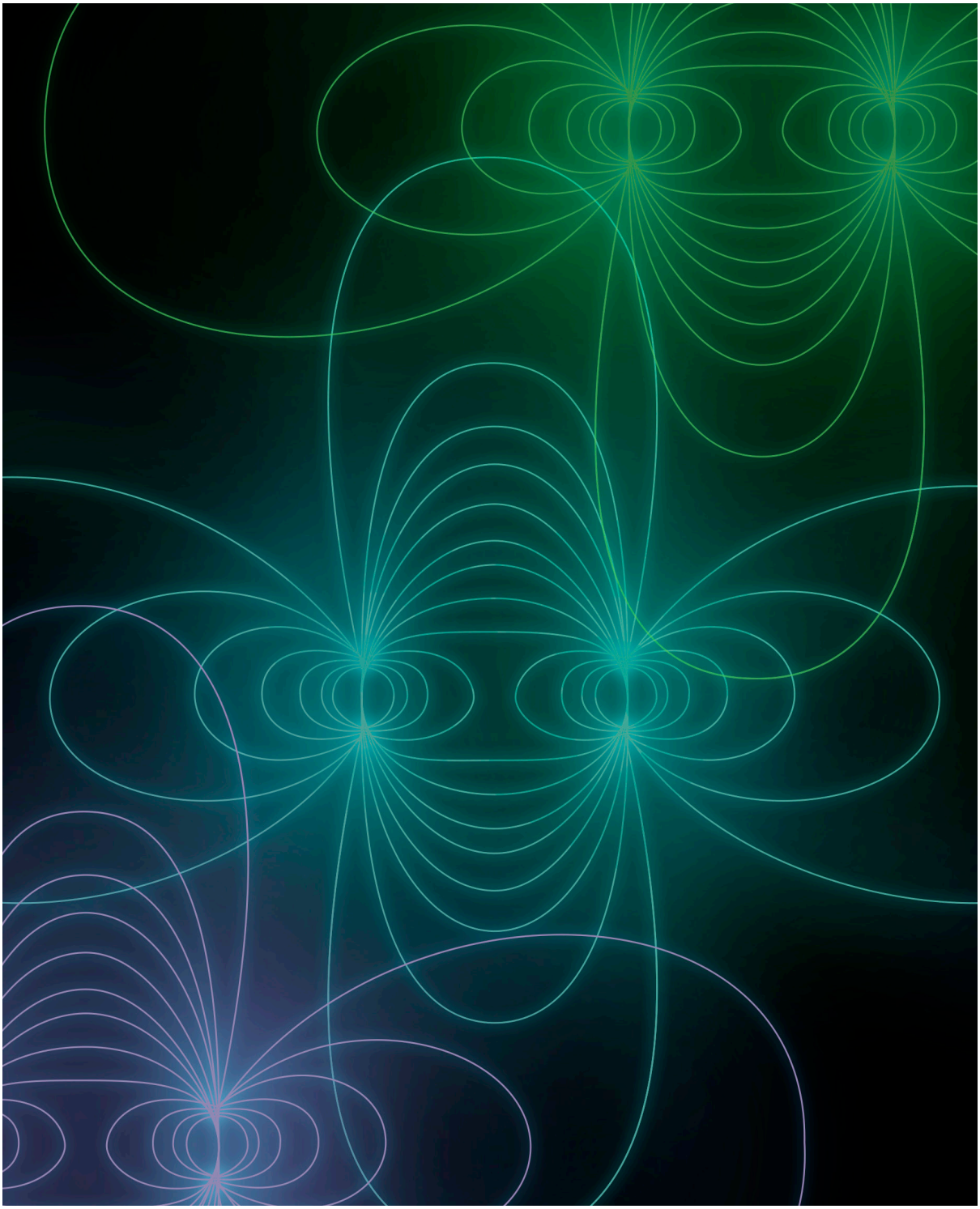
61. Schaefers G. Testing MR safety and compatibility: an overview of the methods and current standards. IEEE Eng Med Biol Mag. 2008;27(3):23-7.

62. Piersson AD, Gorleku PN. A national survey of MRI safety practices in Ghana. Heliyon. 2017;3(12):e00480.

63. Childs S, Bruch P. Successful management of risk in the hybrid OR. AORN J. 2015;101(2):223-34; quiz 35-7.
64. Schaefer DJ, Bourland JD, Nyenhuis JA. Review of patient safety in time-varying gradient fields. J Magn Reson Imaging. 2000;12(1):20-9.
65. Shellock FG, Ziarati M, Atkinson D, Chen DY. Determination of gradient magnetic field-induced acoustic noise associated with the use of echo planar and three-dimensional, fast spin echo techniques. J Magn Reson Imaging. 1998;8(5):1154-7.
66. Ferris NJ, Kavnoudias H, Thiel C, Stuckey S. The 2005 Australian MRI safety survey. AJR Am J Roentgenol. 2007;188(5):1388-94.
67. Keevil S. Safety in magentic resonance imaging. MPI Journal. 2016;4(1):26-34.
68. American College of Radiology. MR-Safety-Screening-Form. 2020;Avalible via https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/MR-Safety-Screening-Form.pdf?la=en.
69. Safety ACRCoM, Greenberg TD, Hoff MN, Gilk TB, Jackson EF, Kanal E, McKinney AM, et al. ACR guidance document on MR safe practices: Updates and critical information 2019. J Magn Reson Imaging. 2020;51(2):331-8.
70. Weidman EK, Dean KE, Rivera W, Loftus ML, Stokes TW, Min RJ. MRI safety: a report of current practice and advancements in patient preparation and screening. Clinical imaging. 2015;39(6):935-7.
71. Jabehdar Maralani P, Schieda N, Hecht EM, Litt H, Hindman N, Heyn C, et al. MRI safety and devices: An update and expert consensus. J Magn Reson Imaging. 2019.
72. German Ultrahigh Field Imaging G. Approval of subjects for measurements at ultra-high-field MRI. 2016;Avalible vis: https://mr-gufi.de/images/documents/Approval_of_subjects_for_measurements_at_UHF.pdf.
73. Dula AN, Virostko J, Shellock FG. Assessment of MRI issues at 7 T for 28 implants and other objects. AJR Am J Roentgenol. 2014;202(2):401-5.
74. Feng DX, McCauley JP, Morgan-Curtis FK, Salam RA, Pennell DR, Loveless ME, et al. Evaluation of 39 medical implants at 7.0 T. Br J Radiol. 2015;88(1056):20150633.
75. Sawyer-Glover AM, Shellock FG. Pre-MRI procedure screening: recommendations and safety considerations for biomedical implants and devices. J Magn Reson Imaging. 2000;12(3):510.
76. Safety ACR Committee on MR Safety. ACR Manual on MR Safety 20201-56. 2020 ; Avalible via : https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf.
77. Kalisch BJ. Missed nursing care: a qualitative study. J Nurs Care Qual. 2006;21(4):306-13; quiz 14-5.
78. Kalisch BJ, Xie B. Errors of Omission: Missed Nursing Care. West J Nurs Res. 2014;36(7):875-90.
79. Dabney BW, Kalisch BJ, Clark M. A revised MISSCARE survey: Results from pilot testing. Appl Nurs Res. 2019;50:151202.
80. VHA National patient safety improvement handbook. R P, editor. Department of veterans affairs veterans health administration, Washington DC2011.

81. Hansson B, Olsrud J, Wilen J, Owman T, Hoglund P, Bjorkman-Burtscher IM. Swedish national survey on MR safety compared with CT: a false sense of security? European radiology. 2020;30(4):1918-26.
82. Mian OS, Glover PM, Day BL. Reconciling Magnetically Induced Vertigo and Nystagmus. Front Neurol. 2015;6:201.
83. Ward BK, Roberts DC, Della Santina CC, Carey JP, Zee DS. Vestibular stimulation by magnetic fields. Annals of the New York Academy of Sciences. 2015;1343:69-79.
84. Davids M, Guerin B, Vom Endt A, Schad LR, Wald LL. Prediction of peripheral nerve stimulation thresholds of MRI gradient coils using coupled electromagnetic and neurodynamic simulations. Magn Reson Med. 2019;81(1):686-701.
85. Hansson B, Markenroth Bloch K, Owman T, Nilsson M, Latt J, Olsrud J, et al. Subjectively Reported Effects Experienced in an Actively Shielded 7T MRI: A Large-Scale Study. J Magn Reson Imaging. 2020;20:1-12. Online ahead of print.
86. Hansson B, Hoglund P, Markenroth Bloch K, Nilsson M, Olsrud J, Wilen J, et al. Short-term effects experienced during examinations in an actively shielded 7 T MR. Bioelectromagnetics. 2019; 40(4):234-249.
87. Moelker A, Pattynama PM. Acoustic noise concerns in functional magnetic resonance imaging. Hum Brain Mapp. 2003;20(3):123-41.
88. Blankholm AD, Hansson B. Incident reporting and level of MR safety education: A Danish national study. Radiography 2019;26(2):147-153.
89. Calamante F, Ittermann B, Kanal E, Inter-Society Working Group on MRS, Norris D. Recommended responsibilities for management of MR safety. J Magn Reson Imaging. 2016;44(5):1067-9.
90. James JT. A new, evidence-based estimate of patient harms associated with hospital care. J Patient Saf. 2013;9(3):122-8.
91. MHRA Medicines and healthcare products regulatory agency L. Safety guidelines for magnetic resonance imaging equipment in clinical use. 2015; Available via: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/476931/MRI_guidance_2015_-_4-02d1.pdf.
92. Edmondson AC. Learning from failure in health care: frequent opportunities, pervasive barriers. Qual Saf Health Care. 2004;13 Suppl 2:ii3-9.
93. Schultz SR, Watson RE, Jr., Prescott SL, Krecke KN, Aakre KT, Islam MN, et al. Patient safety event reporting in a large radiology department. AJR Am J Roentgenol. 2011;197(3):684-8.
94. Price MR, Williams TC. When Doing Wrong Feels So Right: Normalization of Deviance. J Patient Saf. 2018;14(1):1-2.
95. Dempsey MF, Condon B, Hadley DM. MRI safety review. Semin Ultrasound CT MR. 2002;23(5):392-401.
96. Banja J. The normalization of deviance in healthcare delivery. Bus Horiz. 2010;53(2):139.
97. Patient Safety Authority P. Applying the Universal Protocol to Improve Patient Safety in Radiolgy Services. 2011;Avalibel via: http://patientsafety.pa.gov/ADVISORIES/documents/201106_63.pdf.

98. van Osch MJ, Webb AG. Safety of Ultra-High Field MRI: What are the Specific Risks? Curr Radiol Rep. 2014;2(61):1-8.
99. Ward P. Police investigate serious MRI accident in Sweden. AuntMinnieEurope. 2019;Avalible via: https://www.auntminnieeurope.com/index.aspx?sec=sup&sub=mri&pag=dis&ItemID=618002.



LUND UNIVERSITY

FACULTY OF MEDICINE

Department of clinical sciences, Lund

Lund University, Faculty of Medicine
Doctoral Dissertation Series 2020:85
ISBN 978-91-7619-947-3
ISSN 1652-8220