


Subjectively Reported Effects Experienced in an Actively Shielded 7T MRI: A Large-Scale Study

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Background: Ultrahigh-field (UHF) MRI advances towards clinical use. Patient compliance is generally high, but few large-scale studies have investigated the effects experienced in 7T MRI systems, especially considering peripheral nerve stimulation (PNS) and caregiving.

Purpose: To evaluate the quantity, the intensity, and subjective experiences from short-term effects, focusing on the levels of comfort and compliance of subjects.

Study Type: Prospective.

Population: In all, 954 consecutive MRIs in 801 subjects for 3 years.

Field Strength: 7T.

Assessment: After the 7T examination, a questionnaire was used to collect data.

Statistical Tests: Descriptive statistics, Spearman's rank correlation, Mann-Whitney *U*-test, and *t*-test.

Results: The majority (63%) of subjects agreed that the MRI experience was comfortable and 93% would be willing to undergo future 7T MRI as a patient (5% undecided) and 82% for research purposes (12% undecided). The most common short-term effects experienced were dizziness (81%), inconsistent movement (68%), PNS (63%), headache (40%), nausea (32%), metallic taste (12%), and light flashes (8%). Of the subjects who reported having PNS (*n* = 603), 44% experienced PNS as "not uncomfortable at all," 45% as "little or very little uncomfortable," and 11% as "moderate to very much uncomfortable." Scanner room temperature was experienced more comfortable before (78%) than during (58%) examinations, and the noise level was acceptable by 90% of subjects. Anxiety before the examination was reported by 43%. Patients differed from healthy volunteers regarding an experience of headache, metallic taste, dizziness, or anxiety. Room for improvement was pointed out after 117 examinations concerning given information (*n* = 73), communication and sound system (*n* = 35), or nursing care (*n* = 15).

Data Conclusion: Subjectively reported effects occur in actively shielded 7T MRI and include physiological responses and individual psychological issues. Although leaving room for improvement, few subjects experienced these effects being so uncomfortable that they would lead to aversion to future UHF examinations.

Level of Evidence: 1

Technical Efficacy: Stage 5

J. MAGN. RESON. IMAGING 2020.

Magnetic resonance imaging (MRI) with ultrahigh-fields (UHF) has improved the depiction of morphologic changes^{1,2} and has given us new insights in pathophysiology.³ UHF MRI has advanced from research use only to use in the

clinic, and patient compliance, experience of effects, and safety must be carefully considered. Experienced effects and MRI safety risks at all field strengths involve mainly three types of electromagnetic field exposure. The static magnetic

View this article online at wileyonlinelibrary.com. DOI: 10.1002/jmri.27139

Received Dec 27, 2019, Accepted for publication Mar 3, 2020.

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field (causing, for example, projectile risk)^{4–6} or translational forces and dizziness/vertigo originating from Lorenz forces due to ionic currents within the vestibular system,⁷ the radio-frequency field (causing, for example, energy deposition, possible burns, or increase of temperature), and the gradient field (causing, for example, peripheral nerve stimulation [PNS] and acoustic noise).^{4–6}

Previous publications have shown that short-term effects—dizziness/vertigo, inconsistent movement, nausea, headache, and a metallic taste—may be experienced by subjects in the 7T environment,^{8–14} but fewer sensations have been reported in the 1.5T environment, and with considerably (mean 84%) lower mean scores.¹⁰ Evaluation often needs to rely on self-reporting of these effects, which further are often highly subjective, although in general are physiological and may, by some individuals, even be experienced in mock scanners with no static magnetic field, radiofrequency field, or gradient field.^{15,16} Sensations might thus also be influenced by factors in the MRI environment that are not related to the MRI fields, such as experience of discomfort or anxiety.

The purpose of this large-scale study was to investigate the quantity of, the intensity of, and subjective experiences from the effects of 7T MRI, focusing on patient comfort and compliance.

Material and Methods

Ethics

The study was approved by the appropriate Ethics Committee (entry nos. 2015/434 and 2016/126) and informed written consent was obtained from all subjects, as described by Hansson et al.¹⁴

MRI System

Examinations were conducted in first-level controlled operating mode on an actively shielded 7T MRI 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/s, or maximum amplitude 60 mT/m and maximum slew rate 100 mT/m/s; 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) was used for the brain examinations; 28Rx Knee Coil QED (Quality Electrodynamics, Mayfield Village, OH) was used for the knee examinations; 16Rx wrist array (RAPID MRI International, Columbus, OH) was used for the wrist examinations; 8Rx Breast array (RAPID MRI International, Columbus, OH) was used for the breast examinations; and 8Rx C-spine coil (Life Services, Minneapolis, MN) was used for the c-spine examination. Scan protocols varied largely for different body parts and projects, including healthy research subjects

and patients examined at the facility. Projects aimed at technical development, disease-oriented research (eg, systemic lupus erythematosus, epilepsy, brain tumors, dementia, psychiatric disorders, knee arthrosis), and neuroscience research (eg, cognition, motor skills, fear). The sequences used were both manufacturer-provided and programmed in-house. All scans were performed at first-level controlled operating mode and did not exceed the specific absorption rate (SAR) limit of whole-body 4 W/kg or head 3.2 W/kg. Used sequences ranged from standard morphological sequences to ultrashort echo time sequences and to functional, diffusion, perfusion, spectroscopy, flow, and chemical exchange saturation transfer MRI.

Study Subjects and Definition of Data Collected

Over a 3-year period, 1290 research and clinical 7T MRI examinations were performed and all subjects were invited to fill out the web-based questionnaire. Data on inclusion and exclusion of subjects and subject and examination demographics are given in Fig. 1. The participation rate was 74% (954 examinations, 801 individual subjects). The main reasons identified by staff for exclusion were unwillingness to participate due to time concerns, and earlier participation for subjects who underwent several 7T MRs (mainly healthy volunteers). A smaller portion of subjects could not participate due to their disease, due to being too tired, or because they did not feel capable of filling out the questionnaire under the prevailing circumstances (mainly patients). Of the questionnaires submitted, 3% had to be excluded due to being incomplete. For 627 examinations (66%) log files of the highest predicted PNS values could be retrieved, where 100% corresponds to 50% of subjects predicted to experience PNS, defined as anything between a mild tingling and painful contractions of muscles.

This study did not make use of examinations included in a previous study¹⁴ and the questionnaire was updated with additional questions regarding experience and anxiety, and by exclusion of the visual analog scale (VAS) in favor of a six-point Likert scale and a seven-point adjectival scale.¹⁷ Before the examination, all of the subjects underwent a strict MRI safety check, changed from their street clothes to hospital pants and gown, and were provided with hearing protection as in a previous study.¹⁴ After the examination, a web-based questionnaire (REDCap; research electronic data capture; <http://project-redcap.org>) was used to collect data on demographics (gender (M/F), age (y), self-estimated sensitivity regarding motion sickness (kinetosis), on any short-term effects, and on body and room temperature experienced, scanner noise, the communication system, and willingness regarding any future 7T MRI examination. The operator entered the information on session parameters including the length of the examination (min), the part of the body that was examined, and the orientation of the body in the field (head-first or feet-first). Experience of the short-term effects dizziness, inconsistent movement, nausea, headache, and

Examinations performed n = 1290		No participation – exclusion n = 295	
Submitted questionnaires n = 995		Incomplete questionnaires – exclusion n = 41	
Complete questionnaires n = 954		Subjects n = 801	
Healthy volunteer exams n = 682		Gender, mean age (range)	
Study or clinical patient exams n = 272		men n = 425, 35 (14-81) years	
Duration of exams		women n = 376, 35 (14-82) years	
30-60 min n = 649		Examinations per subject	
> 60 min n = 285		1 exam n = 710	
< 30 min n = 20		2 exams n = 71	
Exams per body part		3 exams n = 6	
(n with contrast media)		4 exams n = 6	
brain n = 861 (22)		5 exams n = 3	
knee n = 55 (18)		8 exams n = 2	
wrist n = 34 (0)		9 exams n = 2	
breast n = 3 (0)		10 exams n = 1	
cervical spine n = 1 (0)			
PNS log files			
yes n = 627			
available			
no (subevaluation exclusion) n = 327			

FIGURE 1: Chart of subjects and examinations included and excluded, subject and examination demographics including gender, age, patient status, and number of examinations per individual, duration of examinations, part of the body examined, and whether or not PNS log files were available.

metallic taste were evaluated for four situations: lying on the table and moving into the scanner (in), being at the isocenter (inside), moving out of the scanner (out), and having gone outside the scanner room after the examination (outside), in accordance with a previous study.¹⁴ These short-term effects, together with light flashes, self-estimated sensitivity regarding motion sickness, and PNS were evaluated regarding quantity and/or intensity using a six-point Likert scale: none, very little, little, moderate, much, and very much.¹⁷ The term “inconsistent movement” refers to the experience of body movement in a direction other than the straight direction through the scanner tunnel,¹⁴ and dizziness includes vertigo but also the feeling of presyncope, or disequilibrium and nonspecific feelings difficult for participants to describe or define as vertigo.

Experiencing of room and body temperature before, during, and after research examinations was measured using a seven-point adjectival scale¹⁷ (uncomfortably cold, cold, slightly cold, comfortable, slightly warm, warm, and uncomfortably warm). Tolerance of maximum experienced scanner noise, functioning of the communication system, view of information from and contact with personnel, and willingness regarding future 7T MRI examinations as a research subject or as a clinical patient were measured with a six-point adjectival scale (strongly agree, agree, mildly agree, mildly disagree, disagree, and strongly disagree). At the end of the questionnaire, a free text option gave participants the opportunity to comment on information they had been lacking or suggestions for improvement.

Statistics

Descriptive statistics were used to present data. Nonparametric Spearman's rank correlation was used for analysis of ranked variables such as self-estimated sensitivity regarding motion sickness, highest recorded predicted PNS values, and quantity and intensity of different effects. Any P -value < 0.05 was regarded as being statistically significant. The Mann-Whitney U -test was used to analyze differences in experience of effects between patients and healthy volunteers. A t -test was used to analyze the difference in anxiety levels between the first and second 7T examinations of the subjects who underwent more than one 7T examination.

Results

The proportion of subjects who experienced a short-term effect at any time (moving in, inside, moving out of the scanner, or being outside of the scanner after the examination) during individual examinations was 81% for dizziness, 68% for inconsistent movement, 63% for PNS, 40% for headache, 32% for nausea, 12% for metallic taste, and 8% for light flashes. The quantity and intensity of dizziness, inconsistent movement, nausea, headache, and metallic taste in relation to movement and position in and outside the scanner is summarized in Fig. 2. 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

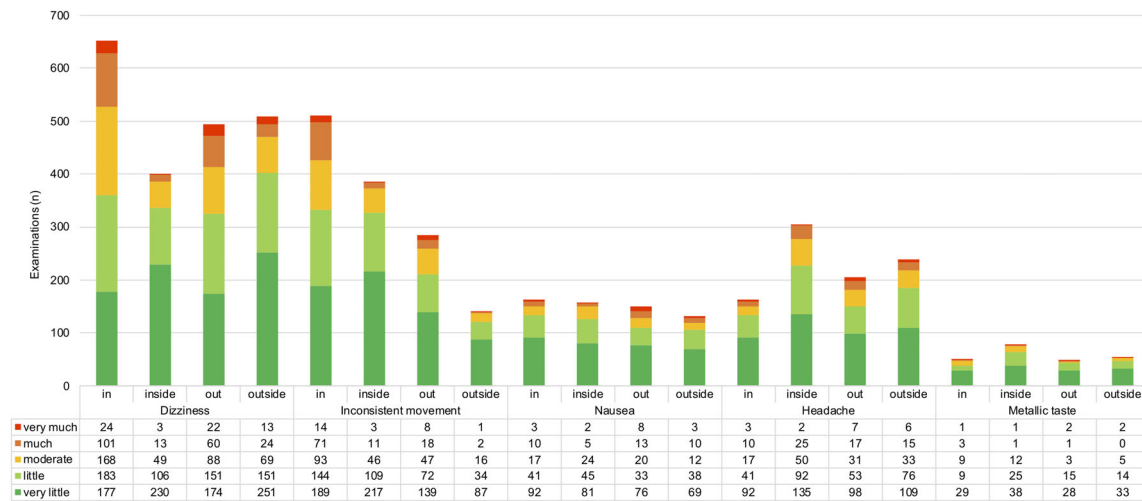


FIGURE 2: Reported quantity and intensity (n examinations) of dizziness, inconsistent movement, nausea, headache, and metallic taste, given in relation to movement (in and out of the scanner) and position (inside and outside of the scanner).

taste ($P < 0.01$; outside the scanner) but less intense dizziness ($P = 0.01$; outside) compared to healthy volunteers (Table 1).

Analysis of the correlation between intensity of self-estimated sensitivity regarding motion sickness and the highest intensity of relevant short-term effects—during movement into the scanner or out of the scanner, or positioned in the scanner—with Spearman's rank correlation showed significant ($P < 0.001$) but very weak to weak correlations for nausea ($\rho = 0.24$), dizziness ($\rho = 0.22$), and inconsistent movement ($\rho = 0.21$).

Descriptive statistics for intensity of self-estimated sensitivity regarding motion sickness and intensity of relevant short-term effects are given in Table 2.

Subjects experienced light flashes in 80 examinations (8%) and rated the quantity as very little in 54 examinations, little in 17 examinations, moderate in six examinations, and much in one examination, with two examinations lacking data on quantity. Intensity was rated as very little in 51 examinations, little in 21 examinations, moderate in six examinations, and much in two examinations, with four examinations lacking data on intensity.

For 598 of the examinations (63%), 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 Fig. 3, differentiating data for examinations for which scanner log files were available ($n = 627$) from data for examinations for which such files were not available ($n = 327$)—for consideration of possible selection bias. 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 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 ($\rho = 0.23$). The relationships between the quantity and intensity of PNS experienced, the highest predicted PNS values, and how uncomfortable the PNS experienced was are illustrated in Fig. 4. Experience of PNS did not differ between patients and healthy volunteers (Table 1).

Scanner room temperature was generally experienced as being more comfortable before than during examinations, while the subject was inside the tunnel. The change in room temperature most commonly reported was a change towards warmer room temperature (338 subjects, as compared to 107 subjects who reported experiencing a decrease in room temperature). Table 3 is a summary of how subjects experienced scanner room temperature before, during, or after the examination and in which parts of the body a temperature change was felt during the examination. Experience of temperature did not differ between patients and healthy volunteers. The change in body temperature experienced was higher (warmer) for 374 subjects and lower for 119 subjects. 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.

Table 4 is a summary of data on acceptability of maximum scanner noise levels, functioning of the communication system, view of information, and contact with personnel and shows that patients and healthy volunteers in 80% to 99% of the examinations agreed or strongly agreed on a positive perception of these aspects. Further, 57% of patients and 65% of healthy volunteers agreed or strongly agreed that the

TABLE 1. Mann Whitney U-Test ($P < 0.05$ Is Considered Significant and Marked Bold) of Difference Between Reported Effects Comparing Patients ($n = 272$) to Healthy Volunteers ($n = 682$)

Effect	Motion (in/out) or location (inside, outside) of the scanner	Difference between patients and healthy volunteers, P -value*	
		Number of subjects experiencing the effect	Reported intensity of the effect
Dizziness	In	0.3	0.6
	Inside	0.2	0.5
	Out	0.1	0.5
	Outside	0.08	0.01*
Inconsistent movement	In	0.08	0.2
	Inside	0.9	0.4
	Out	0.9	1.0
	Outside	0.1	0.09
Nausea	In	0.5	0.6
	Inside	0.3	0.4
	Out	0.3	0.3
	Outside	0.4	0.4
Headache	In	0.002**	0.001**
	Inside	0.005**	0.002**
	Out	0.003**	0.001**
	Outside	0.003**	0.001**
Metallic taste	In	0.4	0.4
	Inside	0.6	0.6
	Out	0.5	0.5
	Outside	0.008**	0.007**
PNS	Inside	0.9	1.0
		Number of Twitches Experienced	Experienced Discomfort Level
PNS	Inside	0.4	0.2

*Intensity for healthy volunteers > patients.
 **Number of affected subjects and intensity for patients > healthy volunteers.

examination was comfortable and willingness to undergo future 7T examinations for research purposes and 82% was for clinical purposes 93%. Subjects who had experienced a previous MRI examination—which was true for 644 of all the examinations (77%)—rated the 7T MRI experience as being worse than previous MRI examinations ($n = 174$ examinations; 27%), as being the same as in previous MRI examinations ($n = 323$ examinations; 50%), and as being better than in previous MRI examinations ($n = 147$ examinations; 23%).

Anxiety before the examination was reported by 412 of the subjects (43%) (Fig. 5) with a mean anxiety level of 1.8 on a 6-grade Likert scale^{1–6} for patients and a mean anxiety level of 1.6 for healthy volunteers. The difference in anxiety level reported by patients and healthy volunteers was significant, with a higher anxiety level for patients prior to the 7T MRI 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. Anxiety levels were not significantly different between

TABLE 2. Intensity of Self-Estimated Sensitivity Regarding Motion Sickness vs. Intensity of Short-Term Effects Given for the 954 Examinations Included in the Study

Short-term effect	Intensity of short-term effect (maximum grade experienced during motion in and out of the scanner and position inside the scanner)	Self-estimated sensitivity regarding motion sickness (<i>n</i> examinations per score)					
		None	Very little	Little	Moderate	Much	Very much
Dizziness	None	127	37	31	13	10	5
	Very little	83	63	19	9	9	6
	Little	80	50	31	30	15	2
	Moderate	61	42	32	29	16	1
	Much	38	26	18	12	15	9
	Very much	11	5	4	6	5	4
Inconsistent movement	None	171	68	29	22	18	6
	Very little	91	54	31	25	16	4
	Little	71	47	32	30	13	6
	Moderate	43	34	22	8	11	7
	Much	20	17	19	11	8	2
	Very much	4	3	2	3	4	2
Nausea	None	321	151	91	60	33	12
	Very little	43	39	22	19	17	2
	Little	19	20	12	6	10	2
	Moderate	14	11	8	6	6	4
	Much	1	1	0	8	3	4
	Very much	2	1	2	0	1	3

the 3 years of the study (Fig. 6). Subjects who had more than one 7T examination ($n = 91$; 10%) had the same anxiety score before the second examination as before the first examination in 67 cases (74%), a lower score in 17 cases (19%; 1 case being a patient), and a higher score in seven cases (7%). There was no significant difference in the anxiety levels reported before the first examination and the anxiety levels reported before the second examination (t -test, $P = 0.3$) in the 91 subjects who underwent more than one 7T examination. The statement that the total experience of the MRI examination was comfortable was strongly agreed or agreed with by 600 subjects (63%), whereas 246 (26%) neither agreed nor disagreed with this, and 108 (11%) disagreed or strongly disagreed (Table 3). Further, there was a significant difference in the comfort rate between patients and healthy volunteers ($P = 0.007$), with healthy volunteers experiencing the 7T examination as more comfortable compared to patients.

In the optional free text at the end of the questionnaire, comments on potential improvements were suggested

regarding 117 examinations; seven were positive comments, for example, that nothing required to be improved or that the hearing protection was very good. Improvements regarding information were suggested by 60 subjects, mainly regarding giving of information on when it was possible to adjust body position; remaining time; and warning prior to sequences with high acoustic noise levels or high risk of PNS. In 13 cases, the proposals for improvement concerned information specific to the study that the subjects were being scanned for. Thirty-five were complaints regarding poor sound quality or the volume of the communication system and/or music system. Fifteen were nursing care-related suggestions, mainly concerning better hearing protection.

Discussion

When UHF is used clinically, it is essential to minimize any undesired effects and optimize compliance. In addition to dizziness, and inconsistent movement, PNS is one of the most

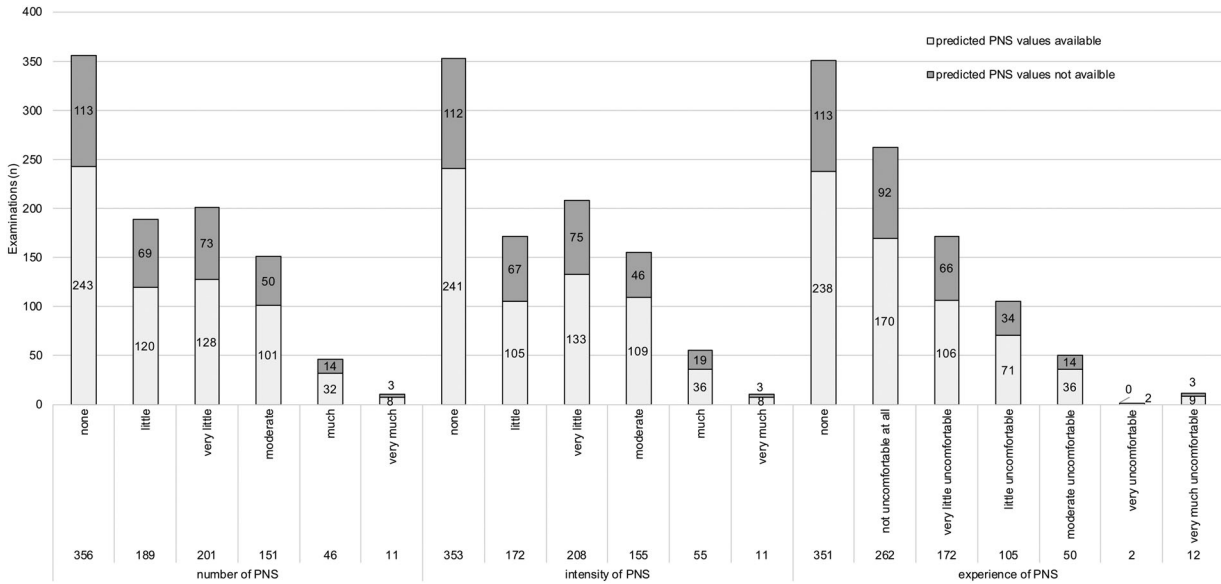


FIGURE 3: Descriptive statistics for quantity and intensity (none – very much) of PNS and how PNS was experienced (not uncomfortable at all – very much uncomfortable), shown for examinations for which predicted PNS values from scanner log files were available ($n = 627$) or not available ($n = 327$).

frequent undesired effects, despite vendor-implemented steps to limit its occurrence. However, most subjects who experience PNS report it as being “not uncomfortable at all” or “very little uncomfortable.” This is in line with an overall high level of acceptance for UHF examinations both for patients and healthy volunteers. Regarding compliance and nursing care issues, the study revealed that data on the 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 UHF examinations.

In comparison to an initial study,¹⁴ most short-term effects that occurred during the movement of the subject into the scanner bore were less prevalent; dizziness had decreased

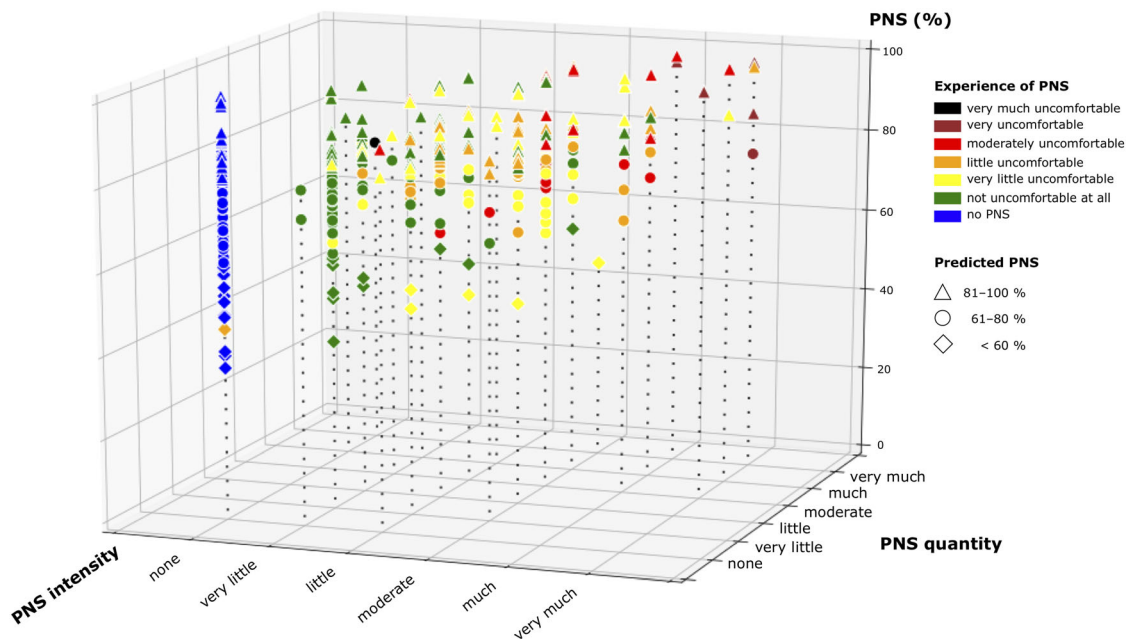


FIGURE 4: Relationship between quantity of PNS, intensity of PNS, predicted PNS values, and the individual experience of PNS for examinations for which predicted PNS values were available ($n = 627$). Three different predicted PNS levels are divided into three groups. The different groups are shown as squares, circles, and triangles.

TABLE 3. Scanner Room Temperature and General Body Temperature Experienced Before, During, and After Scanning, and Temperature Change Experienced in Particular Parts of the Body During the Examination

	Timepoint before, during, after exam	Temperature score, <i>n</i> all examinations (<i>n</i> patient examinations)						
		Uncomfortably Cold	Cold	Slightly Cold	Comfortable	Slightly Warm	Warm	Uncomfortably Warm
Scanner room temperature experienced	Before	2 (0)	27 (12)	148 (52)	746 (200)	27 (7)	4 (1)	0 (0)
	During	6 (2)	26 (12)	112 (34)	556 (161)	161 (44)	74 (15)	19 (4)
	After	2 (0)	47 (23)	198 (48)	639 (188)	50 (10)	17 (3)	1 (0)
Body temperature experienced	Before	3 (1)	27 (7)	69 (24)	805 (222)	43 (16)	5 (2)	2 (0)
	During	4 (2)	42 (14)	67 (20)	488 (145)	245 (61)	92 (26)	16 (4)
	After	1 (0)	37 (16)	101 (27)	685 (189)	107 (30)	20 (9)	3 (1)
Body part experiencing largest temperature change	During	Temperature change score (<i>n</i> examinations)						
		Uncomfortably Colder	Colder	Slightly Colder	No Change*	Slightly Warmer	Warmer	Uncomfortably Warmer
Face		0	0	1	892	43	14	4
Head		0	1	1	888	42	17	5
Arms		0	3	5	896	32	15	3
Hands		2	5	8	917	17	5	0
Torso		0	0	1	924	22	7	0
Spine		0	0	0	941	8	5	0
Pelvis		0	0	0	952	2	0	0
Legs		0	1	6	925	20	2	0
Feet		2	25	42	875	8	2	0

*In 578 examinations, the subjects did not experience any temperature change in a specific body part.

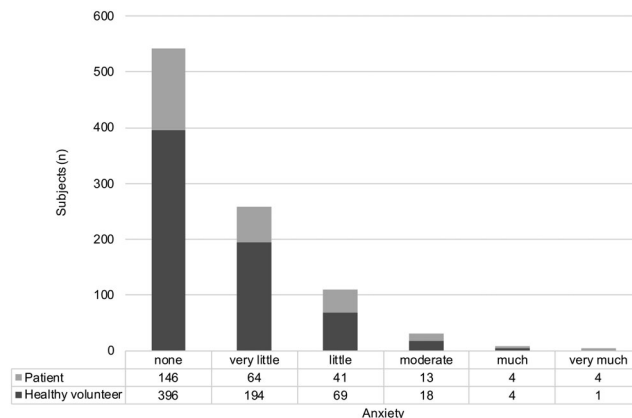
TABLE 4. Acceptability of Noise Level, Information, and Contact With Personnel, Functioning of Communication System, and Willingness to Have a Future 7T Examination

Statement evaluated		Level of agreement, <i>n</i> All examinations (<i>n</i> patient examinations)				
		Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
The maximum noise level was acceptable.		315 (79)	447 (138)	100 (25)	78 (23)	14 (7)
I did feel well-informed and had good contact with personnel.	Before scan	778 (207)	166 (60)	6 (3)	4 (2)	0 (0)
	During scan	703 (182)	227 (79)	16 (5)	5 (4)	3 (2)
The communication system worked well.		376 (88)	443 (130)	69 (25)	60 (24)	6 (5)
The examination was comfortable		203 (49)	397 (105)	246 (79)	96 (31)	12 (8)
I would be willing to have a future 7T MR.	For research	445 (98)	340 (109)	115 (42)	36 (10)	18 (13)
	As a patient *	591 (148)	299 (105)	47 (15)	11 (2)	3 (2)

*Three missing.

from 84% to 68%; inconsistent movement from 70% to 54%; nausea from 52% to 23%; headache from 52% to 17%; and metallic taste from 43% to 5%. The numbers are still high in comparison to other publications.^{12,13,18,19} Compared to the earlier publication,¹⁴ the decrease in frequency of some of the short-term effects might partly be related to the change from using a VAS (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. 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, so the subjects have more time to adapt to a higher field before going into the scanner.^{14,20,21} To establish if differences in experience of effects do exist between actively vs. older passively shielded MRI scanners is mainly relevant from the perspective on how to translate established knowledge between such systems. Direct comparison is difficult, as large patient groups are required and scanners often differ regarding, not only in shield coils and resulting fringe fields, but also other aspects, as for example gradient coil design. We therefore advocate exploration of further large-scale populations from different types of actively shielded UHF systems.

**FIGURE 5: Preexamination anxiety levels in healthy volunteers and patients.**

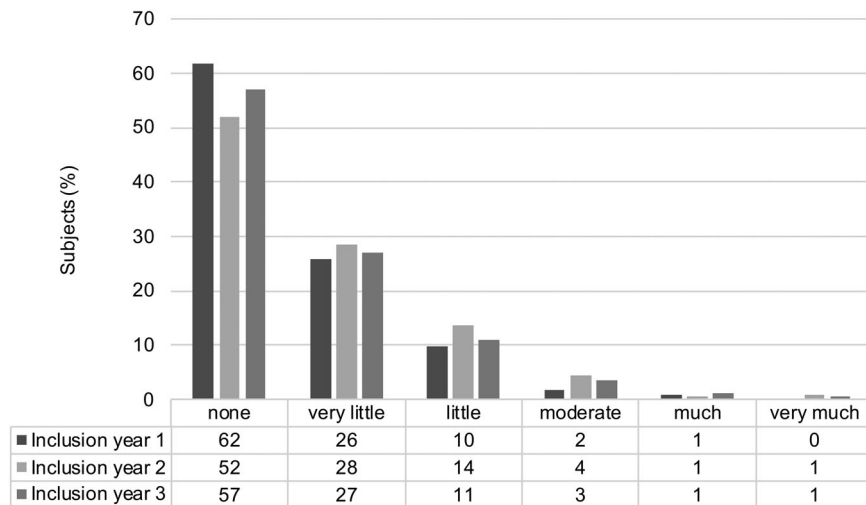


FIGURE 6: Preexamination anxiety levels in subjects for the 3 years of inclusion.

The proportion of subjects who reported PNS was higher than in earlier publications^{11,12,22} but was very similar to that in our previous study (63% and 67%, respectively), without any apparent effect of the change from VAS to step scales. Possible explanations for the high occurrence of PNS with 7T scanners might be the high level of dB/dt for protocols used in research studies,^{14,23} a systematic difference to other systems in terms of geometry, or the current pattern of the gradient coil. 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. Glover²⁴ 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 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 the previous study,¹⁴ the subjects were informed before the examination that PNS might occur, but they were not always prewarned about upcoming sequences when the system warning for high predicted PNS occurred. Subject feedback indicated a preference for being prepared prior to sequences with high predicted PNS. Of the subjects who experienced PNS, 1.5% 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.”

The uncomfortable increase in body temperature experienced in a particular part of the body during the examination could be traced to a specific research protocol where several long functional (f)MRI echo-planar imaging (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, was beyond 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 subject a blanket.

Concerning short-term effects when moving in the tunnel, nausea was not reported as often as dizziness and inconsistent movement, but there was a slightly higher correlation between nausea and self-estimated sensitivity regarding motion sickness. Although considered of relevance in other studies,²⁵ in the present study self-estimated sensitivity regarding motion sickness only showed a very weak to weak correlation with the occurrence of relevant short-term effects, and in our opinion premedication in a research or clinical setting is not indicated based on these correlations, but it might be considered for patients who are predisposed to disease-related nausea—especially in combination with a high self-estimated sensitivity regarding motion sickness.

As in previous studies, light flashes were reported very infrequently.^{12,26} Phosphene is characterized by the experience of seeing light without actual light entering the eye. Magnetophosphene might occur when the retina is magnetically stimulated at a narrow frequency range of around 20 Hz.¹⁶ The absolute majority of the study subjects were examined with the head coil. Investigation of differences in short-term effects depending on the part of the body examined would require a more diverse examination palette than represented in this study, which mainly consisted of brain examinations.

The general experience of having good contact with the personnel before the examination from the reporting in this study is in agreement with the reporting in the previous study¹³—99% and 98%, respectively, with 97% and 95%, respectively, during the examination. This might be a result of a focused effort to educate all personnel who come in contact with research subjects and patients. The noise generated primarily by the gradient system is a well-known issue in MRI. The degree of acceptance of noise levels has improved,

from 74% in the previous study to 90% in the current study. 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 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.

That 644 subjects (67%) had experienced a previous MRI examination might introduce bias regarding the experiencing of 7T MRI. Considering this, however, we regard it notable that 412 of the subjects (43%) showed some level of anxiety before the examination, and that patients were significantly more anxious than volunteers. No significant difference in anxiety levels were observed between the first and second MRI 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 MRI examinations with 30–40%.^{27,28} The main stressor in Lo Re et al.²⁷ was the uncertainty of the diagnosis, therapy, and prognosis. These studies also stress the importance of professionalism of the radiological staff 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.^{27,28}

Improved information, about the examination might reduce preexamination anxiety. To ease anxiety during the examination, some subjects made suggestions regarding the need for more information during the examination; for example, 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 MRI examination both as patient or research subject with a positive attitude. The findings in this study point towards a generally positive attitude towards 7T examinations and high patient comfort also seen by others,^{9–11} but also show that there is absolutely room for improvement when 7T MRI now translates into clinical use.

Limitations

The lack of 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 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 a healthy volunteer or patient, of indications 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 MRI for other reasons than this study, we could not measure vital signs or neurocognitive functions.

It was only possible to retrieve 66% of the examination log files; however, there was no selection bias regarding experiencing of PNS between subjects with log files and those without log files available.

The temperature in the scanner room was not constant during the study, but varied between -17°C and 22°C . The staff compensated for the low temperature by offering the subject a blanket.

Differences in short-term effects depend on the part of the body examined, leading to differences in exposure to the static magnetic field, the gradient field, and the radiofrequency electromagnetic field. To evaluate such differences would require a more diverse examination palette than represented in this study, which mainly consisted of brain examinations.

Some of the aspects evaluated in this study might be influenced by personnel handling the subjects and thus the diversity of personnel: researchers, technicians, MRI physicists, and doctors. We tried to minimize this potential bias, as all personnel at the facility received training from only three technicians who work closely together and supervise or perform a majority of the scans. Examples of aspects that might be influenced by the diversity of personnel are application of hearing protection and communication skills, potentially influencing experience of noise, information, and communication.

Subjectively reported effects occur in actively shielded UHF MRI and include physiological responses and highly individual psychological issues. Although leaving room for improvement, only a few patients and healthy volunteers experienced these effects as being so uncomfortable that they would lead to aversion to future UHF examinations.

Conclusion

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

Acknowledgments

We thank Prof. Peter Höglund, who passed away during the preparation of this article, and we acknowledge his invaluable support and input regarding study design, ethical issues, and

statistical considerations. We thank Birger Balkenius for providing a four-dimensional viewpoint of the relationship between PNS values, quantity, strength, and experience.

Funding

This work was supported by Skåne University Hospital foundations and donations.

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