

# Multicenter Study of Subjective Acceptance During Magnetic Resonance Imaging at 7 and 9.4 T

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**Objectives:** The aims of this study were to investigate the subjective discomfort and sensory side effects during ultrahigh field (UHF) magnetic resonance imaging (MRI) examinations in a large-scale study and to evaluate differences between magnetic resonance (MR) sites.

**Materials and Methods:** Four MR sites with a 7-T MR system and 2 MR sites with a 9.4-T MR system participated in this multicenter study with a total number of 3457 completed questionnaires on causes of discomfort and sensations during the examination. For a pooled retrospective analysis of the results from the partially different questionnaires, all data were adapted to an answer option with a 4-point scale (0 = no discomfort/side effect, 3 = very unpleasant/very strong sensation). To differentiate effects evoked by the low-frequency time-varying magnetic fields due to movement through the static magnetic field, most questionnaires separated the manifestation of sensory side effects during movement on the patient table from manifestation while lying still in the isocenter.

**Results:** In general, a high acceptance of UHF examinations was found, where in 82% of the completed questionnaires, the subjects stated the examination to be at least tolerable. Although in 7.6% of the questionnaires, subjects felt discomfort during the examination, only 0.9% of the image acquisitions had to be terminated prematurely. No adverse events occurred in any of the examinations. Only 1% of the subjects were unwilling to undergo further UHF MRI examinations. Examination duration was the most complained cause of discomfort, followed by acoustic noise and lying still. All magnetic-field-related sensations were more pronounced when moving the patient table versus the isocenter position (19%/2% of the subjects felt unpleasant vertigo during the moving/stationary state). In general, vertigo was the most often stated sensory side effect and was more pronounced at 9.4 T compared with 7 T. However, the results varied substantially among the different sites.

**Conclusions:** The high levels of subjective acceptance found in this study lead to the conclusion that UHF MRI would be tolerated as a diagnostic tool in

clinical practice. For more consistent data ascertainment, we propose a standardized questionnaire for subjective perception monitoring.

**Key Words:** MR safety, sensory side effects, discomfort, high field, questionnaire

(*Invest Radiol* 2014;49: 249–259)

The first 8-T magnetic resonance (MR) scanner for imaging of humans was installed in 1998.<sup>1</sup> Since then, more and more volunteer and patient examinations have been performed with ultrahigh field (UHF) MR systems, that is, MR systems with a static magnetic field strength  $B_0$  above 4 T. There are currently more than 40 UHF MR scanners for human imaging in operation worldwide. These rapid developments have led to increased safety concerns regarding potential risks and health effects associated with the use of MR imaging (MRI). Three types of fields interact with the human body and are responsible for potential hazards during MR procedures: the radiofrequency (RF) electromagnetic field, the alternating magnetic gradient field, and the static magnetic field  $B_0$ . The transmitted RF energy is deposited into the tissue in the form of heat. In UHF MRI, this issue poses a higher risk because the specific absorption rate (SAR) increases theoretically quadratically with the magnetic field strength. However, the behavior also depends on the specific setup (eg, type of RF coil) and the tissue properties (eg, permittivity and the conductivity), which also depend on the RF frequency (eg, Ibrahim<sup>2</sup>). Numerical evaluations have revealed that the required power increases continually with frequency, but at a lower rate at high frequencies,<sup>3</sup> or even starts decreasing at frequencies above 280 MHz.<sup>2</sup> Measurements by Vaughan et al<sup>4</sup> showed that the required RF power at 7 T is approximately 2-fold higher than at 4 T if similar transverse electromagnetic head coils are used. In addition, inhomogeneous power deposition in the examined tissue is caused by nonuniformities in the RF electric field (eg, Vaughan et al<sup>4</sup> and Hoult<sup>5</sup>). However, this should not affect the subjective acceptance of the MRI examination because the same SAR limits are applied as for lower-field-strength MRI. The rapidly switching magnetic gradient fields can provoke peripheral nerve stimulations owing to induced electric currents in the body.<sup>6,7</sup> In UHF MR systems, however, gradient performance is similar to that of modern 1.5- and 3-T systems. Furthermore, the acoustic noise associated with an MR examination is produced through the interaction of the gradient system with the static magnetic field due to Lorentz forces, and the acoustic noise level of UHF MR systems is therefore expected to increase. However, Schmitter et al<sup>8</sup> showed in a 7-T MR system that with protocols where the maximum sound pressure levels were expected (sinusoidal gradient switching with the main frequency component of the readout gradient adapted to the acoustic resonance frequency of the scanner [730–740 Hz]), sound pressure levels up to 112 dB are generated, which is similar to those of a 1.5-T MR system. This moderate sound pressure level can be achieved because 7- and 9.4-T systems possess no body coil, thus enabling additional acoustic insulation. The third issue concerns the

Received for publication July 17, 2013; and accepted for publication, after revision, December 13, 2013.

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Conflicts of interest and source of funding: Jülich has received funding through a BMBF grant, (number 13N9121). All other authors declared no conflicts of interest or funding sources.

Supplemental digital contents are available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site ([www.investigativeradiology.com](http://www.investigativeradiology.com))

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ISSN: 0020-9996/14/4905-0249

static magnetic field and its concomitant effects due to movement in the field. To reflect the existing uncertainty about the potentially harmful effects of electromagnetic fields and to offer flexibility for the development and clinical evaluation of new MR technologies, the safety regulations of the International Electrotechnical Commission give exposure limits for 3 different modes of operation for subjects.<sup>9</sup> The normal mode includes routine MR examinations with magnetic field strengths equal to or below 3 T, the controlled (first-level controlled) mode operates with field strength above 3 T and below or equal to 4 T, and the experimental (second-level controlled) mode describes all examinations with field strengths above 4 T. With the exception of the static magnetic field, operation of commercial UHF MRI systems is in compliance with the requirements of the normal or first-level controlled mode as defined by the International Electrotechnical Commission. In particular, the same SAR and gradient field limits are applied as for lower-field-strength MRI.<sup>10,11</sup>

Therefore, the static magnetic field is expected to be the most relevant factor concerning the subjective acceptance and discomfort during an UHF MRI procedure relative to an MRI procedure at a clinical field strength of 1.5 or 3 T. This includes low-frequency electric currents induced in the subject's body caused by movement within the fringe field of the MR scanner.<sup>12,13</sup> In the United States, the Food and Drug Administration extended the nonsignificant risk status to magnetic field strengths of up to 8 T in July 2003.<sup>14</sup> However, UHF MR systems are currently exclusively used for research purposes, and the acquired data are not intended to be used for diagnostics.

Several MR safety studies on human exposure to high magnetic fields and related biological effects,<sup>15</sup> vital signs,<sup>16,17</sup> cognitive function,<sup>16,18–22</sup> and stress<sup>23</sup> have been published. However, only a few systematic investigations on subjective perception at UHF exist. Cavin et al<sup>24</sup> published thresholds for perceiving metallic taste at 7 T. Glover et al<sup>25</sup> performed experiments on the origin of vertigo due to the movement in the stray field of a 7-T MR system. Other data on subjective perception have been published by Heinrich et al,<sup>18</sup> where 41 young healthy volunteers commented on several sensory

side effects after movement in the stray field of 1.5-, 3-, and 7-T MR systems as well as in a mock scanner at earth's magnetic field serving as control. Only Versluis et al,<sup>26</sup> Theysohn et al,<sup>27</sup> and, subsequently, Heilmaier et al<sup>28</sup> have shown results on general acceptance and discomfort during UHF MR examinations. Heilmaier et al<sup>28</sup> published data regarding 577 subjects who underwent a 7-T MR examination and evaluated their subjective perceptions based on an extensive questionnaire. The aim of our study was to further enhance the data from Heilmaier et al<sup>28</sup> and include questionnaires on discomfort and sensations at UHF from other 7- as well as 9.4-T MR sites in Germany. This first multicenter study also provides further comparisons between the results of the different UHF MR sites, for men versus women and for younger healthy volunteers versus older healthy volunteers and subjects with known diseases.

## MATERIALS AND METHODS

A total of 3467 UHF MR examinations were performed on 1419 subjects (808 men, 611 women; mean age, 34.2 years; range, 18–82 years) at 6 different research sites in Germany; 256 of the 1419 subjects underwent multiple examinations (Table 1). All measurements were conducted using passively shielded whole-body MR systems (Magnetom; Siemens Healthcare, Erlangen, Germany) operating at 7 T (Essen, Heidelberg, Magdeburg, and Leipzig) and 9.4 T (Jülich and Tübingen). All systems were equipped with a gradient system capable of 40 mT/m amplitude and 200 T/m/s slew rate, except the last quarter of examinations from site Leipzig (70 mT/m amplitude) and all examinations from Tübingen (head-only gradient insert: 60 mT/m amplitude, 400 T/m/s slew rate, 32 cm diameter). The transmit/receive RF coils used are listed in Table 2 for all sites. The accessible magnet bore has a diameter of 60 cm (all MR systems) and a length of 340/400/370 cm for all 7 T sites/Jülich/Tübingen, respectively. In all MR systems, a nonmotorized patient table was moved very slowly by hand into the scanner bore to minimize sensory effects due to induced currents and associated electric fields. Earplugs and/or system headphones (Siemens Healthcare and MR confon, Magdeburg, Germany) were used for noise reduction. A 2-way speaker

**TABLE 1.** Study Population, Ranges, and Adaptation of Scale Shown for the Participating Sites

	Essen, 7 T	Heidelberg, 7 T	Magdeburg, 7 T	Leipzig, 7 T	Jülich, 9.4 T	Tübingen, 9.4 T	Total
Number of questionnaires	571	401	113	2062	53	257	3457
Abort	10	5	0	13	2	1	31
Abort without questionnaire	4	3	0	0	2	1	10
Mean age, y*	38.9	39.4	28.2	26.8	33	31.0	30.7
Age range min, y	18	18	23	21	20	23	18
Age range max, y	81	82	33	77	65	45	82
Questionnaires from subjects with known pathology	323	210	0	72	0	0	605
Questionnaires from healthy subjects	248	191	113	1990	53	257	2852
Questionnaires from women	280	171	36	962	9	41	1499
Questionnaires from men	291	230	77	1100	44	216	1958
Number of participating subjects	571	401	66	299	53	29	1419
Subjects with multiple examinations	0	0	55	180	0	21	256
Mean examination duration, min	72	69	75	80	68	93	77
Range of scale	0–10	1–10	Yes/no	0–3	Yes/no	0–3	
Adaptation of scale							
0 = no or very weak sensation/discomfort	0–1	1	No	0	No	0	0
1 = weak sensation/tolerable	2–4	2–4		1		1	1
2 = medium sensation/discomfort	5–7	5–7		2		2	2
3 = strong sensation/discomfort	8–10	8–10		3		3	3

Note that for Magdeburg, Leipzig, and Tübingen, subjects were examined several times, and therefore, the number of questionnaires exceeds the number of subjects.

\*The mean age is given for all questionnaires from the respective site inclusive of the multiple examinations.

TABLE 2. Radiofrequency Coils Used at All Sites

	Essen, 7 T	Heidelberg, 7 T	Magdeburg, 7 T	Leipzig, 7 T	Jülich, 9.4 T	Tübingen, 9.4 T
Circularly polarized (CP) transmit/24-channel or 32-channel receive head coil (Nova Medical, Wilmington, MA), diameter: 18 cm	×	×	×	×		
Transmit/8-channel receive head coil (Rapid Biomedical, Rimpär, Germany), diameter: 25 cm high, 23 cm wide	×		×	×		
10-cm-diameter loop coil (Rapid Biomedical)	×	×				
CP head coil (Invivo, Gainesville, FL), diameter: 26.5 cm	×			×		
CP knee coil (Invivo), diameter: 10 cm	×					
36-cm-diameter CP coil (Siemens Healthcare)	×					
Double-resonant (1H/35Cl) birdcage coil (QED, Mayfield Village, OH), diameter: 25 cm		×				
Double-resonant (1H/23Na) birdcage coil (Rapid Biomedical), diameter: 26 cm		×				
9.4-T single-channel birdcage coil (Rapid Biomedical), diameter: 25 cm high, 23 cm wide					×	
Custom-built coils	Spine array, carotid array, head array (diameter: 26 cm), flexible body array <sup>36-38</sup>	170 birdcage head coil (diameter: 26 cm) <sup>39</sup>			8-channel parallel transmission coil (diameter: 26 cm), <sup>40</sup> 23Na coil array (diameter: 25.5 cm) <sup>41</sup>	16-channel transmit/receive array (diameter: 20.5 cm high, 28 cm wide), 16-channel transmit/31-channel receive array combination (diameter 18.5 cm high, 20 cm wide), patch antenna for traveling wave imaging, 31P-birdcage coil (diameter 26 cm) <sup>42-44</sup>

system and an emergency squeeze bulb were available to ensure communication to the medical staff during the entire examination. The study population for all participating MR sites is given in Table 1; 91% of the examinations (n = 3154) were performed at 7 T, with the remaining 313 examinations performed at 9.4 T. All examinations were approved by the respective local ethics committee at each individual site. All subjects were informed about possible side effects and that the UHF MR images would not be used for individual diagnostics, and all subjects provided written consent before the examination. Contraindications were carefully observed.

### Data From Essen (7 T)

The data from Essen have previously been published by Theysohn et al<sup>27</sup> and Heilmaier et al<sup>28</sup>. The results were included into the multicenter study for comparison with the subjective perception of discomfort at the other UHF sites in Germany. In addition, the data from Essen include the highest number of subjects with known diseases (cf. Table 1), which is an important study group in the context of subjective perceptions. The publication of Heilmaier et al<sup>28</sup> encompasses 575 subjects who had been scheduled for a 7-T examination. As in 4 cases scanning could not be commenced, a total number of 571 examinations were evaluated (ie, 1 examination per subject). Two hundred fifty of these were healthy volunteers and 323 were subjects with known pathologies (mainly benign or malignant tumors and neurological diseases, eg, epilepsy, Parkinson disease, dementia, or multiple sclerosis). A wide range of body regions were imaged (437 head, 105 extremity, and 29 trunk examinations). In 85 subjects, the scan was accomplished in the feet-first supine position;

in 449 subjects, the head-first supine position; and in 37 subjects, the head-first prone position. For more details, see Table 1 and Heilmaier et al.<sup>28</sup>

Depending on the research question and body part examined, various sequences were applied, such as fast-spin-echo techniques, gradient-echo sequences, balanced steady-state free precession sequences, and echo planar imaging (EPI). The mean examination duration was 72 minutes including initial manual shimming of the static magnetic field.

### Questionnaire (Essen)

After the 7-T examination, subjects were asked to fill out an extensive questionnaire covering 10 possible causes of discomfort and 9 sensory side effects (in addition to the sensations listed in Table 3: sweating/sweat attack, headache, fear, tachycardia, and feeling of insubstantiality). The presence of sensory side effects could be stated separately for different examination phases: first, during the slow table movement into and out of the magnet, and second, while lying still in the isocenter during the image acquisition. Thus, it is possible to differentiate between effects evoked by the low-frequency time-varying magnetic fields due to movement through the static magnetic field and the intermediate-frequency magnetic gradients and the high-frequency RF pulses during the image acquisition. All possible sensations were rated on an 11-point scale referring to the intensity level. Causes of discomfort/sensory side effects were rated as follows: 0–1 = not unpleasant at all or mildly unpleasant/no or very weak sensation, 2–4 = tolerable/weak sensation, 5–7 = unpleasant/medium sensation, and 8–10 = very unpleasant/strong sensation.

**TABLE 3.** Causes of Discomfort and Sensations Given in Mean Values of the Grading (Scale, 0-3) and in Percentage of Completed Questionnaires Where Subjects Graded With Intensity Level Greater Than 1, Subdivided for All Participating Magnetic Resonance Sites

	Essen, 7 T		Heidelberg, 7 T		Magdeburg, 7 T	Leipzig, 7 T		Jülich, 9.4 T	Tübingen, 9.4 T		Total	
Number of questionnaires	571		401		113	2062		53	257		3457	
	Mean Score	% >1	Mean Score	% >1	% Yes*	Mean Score	% >1	% Yes*	Mean Score	% >1	Mean Score	%
<b>Causes of discomfort</b>												
Examination duration	1.14	38.2	1.23	39.2	–	0.15†	7.5	–	0.16†	7.8	0.45	16.7
Noise	0.94	28.7	1.11	32.2	–	0.24	2.4	4*	0.53	7.4	0.48	10.9
Lying still	0.83	25.0	0.88	21.0	–	0.30	1.8	–	0.34	3.1	0.46	8.3
Positioning/padding	0.53	12.4	0.84	22.2	–	0.14	1.4	17*	0.39	4.3	0.32	6.3
Room temperature	0.73	23.8	0.61	19.0	–	–	6.4	–	–	5.9	0.68‡	6.3
Bore narrowness	0.76	23.8	0.73	20.7	–	0.06	0.4	–	0.22	2.3	0.27	7.1
General discomfort	0.86	20.3	0.98	19.5	–	0.29	2.3	9*	0.44	3.5	0.47	7.6
Twitching	0.46	13.0	0.66	15.0	15.0*	0.19	4.3	17*	0.35	13.6	0.31	7.7
Less contact	0.46	10.5	0.51	8.7	–	0.13†	6.5	2*	0.09†	4.3	0.23	7.2
Heat	0.41	12.1	0.50	11.2	15.9*	0.16	3.4	4*	0.14	1.2	0.24	5.5
<b>General sensations</b>												
Vertigo	0.78	23.5	0.81	26.9	23.9*	0.57	16.5	43*	0.92	25.7	0.70	20.2
Metallic taste	0.15	2.8	0.24	7.2	11.5*	0.23	5.5	23*	0.32	4.7	0.25	5.6
Nausea	0.18	5.3	0.14	3.5	–	0.05	1.3	–	0.06	1.2	0.09	2.2
Light flashes	0.12	2.8	0.10	2.0	1.8*	0.04	0.7	15*	0.10	2.0	0.08	1.6
<b>Sensations while moving</b>												
Vertigo	0.74	22.1	0.80	26.7	–	0.55	15.9%	–	0.91	25.7	0.64	19.1 <sup>§</sup>
Metallic taste	0.12	2.3	0.17	4.7	–	0.19	4.5	–	0.31	4.7	0.18	4.2 <sup>§</sup>
Nausea	0.16	4.4	0.12	3.0	–	0.04	0.9	–	0.06	1.2	0.07	1.8 <sup>§</sup>
Light flashes	0.11	2.8	0.06	1.0	–	0.02	0.2	–	0.09	1.6	0.05	0.9
<b>Sensations at isocenter</b>												
Vertigo	0.17	4.2	0.15	3.0	–	0.09	1.7	–	0.05	0.4	0.11	2.2
Metallic taste	0.10	2.3	0.15	4.2	–	0.12	2.3	–	0.17	1.2	0.12	2.5
Nausea	0.08	2.5	0.06	1.0	–	0.03	0.5	–	0.00	0.0	0.04	0.9
Light flashes	0.06	0.9	0.07	1.5	–	0.03	0.5	–	0.04	1.6	0.04	0.8

\*Given is the percentage of positive answers.

†3-point scale (range, 0, 2, 3).

‡ Mean score only from data of Essen and Heidelberg.

§ $P < 0.05$  (comparison between moving and stationary patient table of the pooled data). Note: for Magdeburg, Leipzig, and Tübingen, subjects were examined several times.

Space was provided for further comments. In addition, subjects were asked whether they were willing to undergo another UHF MR examination.

### Data From Heidelberg (7 T)

Of 404 scheduled examinations (1 examination per subject), 5 examinations were aborted; however, 2 of the subjects with aborted examinations were willing to answer the questionnaire. From the remaining 401 subjects, a total of 368 subjects underwent head examinations in the head-first supine position and 33 underwent extremity examinations in the feet-first supine position. The study encompasses 191 healthy subjects and 210 subjects with known pathology. Most of the diseased subjects experienced malignant tumor ( $n = 108$ ). Other diseases included neurological diseases ( $n = 33$ ), arteriovenous malformations ( $n = 24$ ), cartilage and muscle diseases ( $n = 24$ ), and other ( $n = 21$ ), such as cerebral hemorrhage.

Several clinical and research pulse sequences were performed: mainly fast-spin-echo and gradient-echo techniques, EPI, and a density-adapted 3-dimensional radial sequence for nonproton imaging.<sup>29</sup> For blood-oxygenation-level-dependent contrast (BOLD) functional MRI (fMRI) measurements, a custom-build in-room monitor<sup>30</sup> was used,

and for arterial spin labeling imaging, the subjects wore the system electrocardiogram unit (Siemens Healthcare). Mean examination duration was 69 minutes.

### Questionnaire (Heidelberg)

Subjects were asked to fill out an extensive questionnaire after the 7-T examination that was designed on the basis of the questionnaire from Essen with the same questions. All possible sensations were rated on a 10-point scale referring to the intensity level. Causes of discomfort/sensory side effects were rated as follows: 1 = not unpleasant/no sensation, 2–4 = tolerable/weak sensation, 5–7 = unpleasant/medium sensation, and 8–10 = very unpleasant/strong sensation.

### Data From Magdeburg (7 T)

Sixty-six subjects were examined several times so that a total number of 113 7-T examinations were carried out (Table 1). None of the examinations were aborted. All subjects were healthy volunteers and underwent BOLD fMRI scans in the head-first supine position. Mainly gradient-echo and EPI pulse sequences were applied. The mean examination duration was 75 minutes.

## Questionnaire (Magdeburg)

After each examination, the volunteers were asked to fill out a questionnaire that included 6 questions covering nervousness before the examination, vertigo, metallic taste, light flashes, feeling of peripheral nerve or muscle stimulation, and feeling of heat or cold. The questions could be answered with a “yes/no/do not know” option. If 1 or more questions were answered with “yes” or “do not know,” the volunteer was asked for further explanation. Supplementary comments could be added. In addition, the volunteers were asked about their willingness to undergo future examinations.

## Data From Leipzig (7 T)

Overall, 246 healthy volunteers and 53 subjects with known diseases participated in the study, which included repeated examinations (mostly in the healthy volunteers), yielding a total number of 2062 examinations (on average, 8 examinations per volunteer; 26 volunteers performed >20 examinations). The pathologies included depression (n = 31), Parkinson disease (n = 9), and congenital blindness (n = 13). Only brain imaging in the head-first supine position was carried out. Depending on the research project, various pulse sequences were applied, such as EPI, various spin-echo and gradient-echo techniques, and diffusion weighted imaging. Several additional MR-compatible devices were used, including pulse oximeter, breathing mask, optical tracking system, and devices for vibrotactile and electrical stimulation. Furthermore, image acquisitions with breathing gases with elevated CO<sub>2</sub> or O<sub>2</sub> content, as well as experiments with hyperventilation, were performed. The mean examination duration was 80 minutes.

## Questionnaire (Leipzig)

The extended questionnaire, which was obtained after every examination, included 19 questions about potential causes of discomfort and sensory side effects (in addition to the sensations given in Table 3: excitement, unusual tiredness, numbness, feeling besotted, and other unusual visual phenomena). Similar to Essen and Heidelberg, the sensory side effects were documented separately for appearance during patient table movement and during the image acquisition. Possible perceptions were rated on a 4-point scale referring to the intensity level. Causes of discomfort/sensory side effects were rated as follows: 0 = not unpleasant/no sensation, 1 = tolerable/weak sensation, 2 = unpleasant/medium sensation, and 3 = very unpleasant/strong sensation. Examination duration and contact to MR personnel were rated on a 3-point scale (duration ok/contact good, duration too long/contact sufficient, and duration much too long/contact very poor). The question about room temperature was answered with a too cold/ok/too warm option without score ranking. Additional comments regarding positioning/padding and other physical sensations could be made. The last question inquired about the willingness to undergo additional future 7-T examinations.

## Data From Jülich (9.4 T)

Fifty-five healthy volunteers were examined on a 9.4-T MR-positron emission tomography hybrid system. All measurements were performed without the positron emission tomography insert. Two subjects aborted the examination because of claustrophobia. The remaining 53 volunteers underwent head examinations in the head-first supine position. Various pulse sequences were applied, such as fast-spin-echo and gradient-echo techniques, EPI, several noncartesian acquisition techniques for <sup>23</sup>Na imaging, and simultaneous single-quantum and triple-quantum-filtered MRI of <sup>23</sup>Na.<sup>31</sup> The mean examination duration was 68 minutes.

## Questionnaire (Jülich)

After the 9.4-T examination, volunteers were asked to fill out a questionnaire that included 7 questions about possible causes of

discomfort and 3 questions about sensory side effects (Table 3). The questions could be answered with a yes/no option. Additional comments could be made.

## Data From Tübingen (9.4 T)

A total of 30 healthy volunteers were scheduled for a 9.4-T examination. Scanning was not started in 1 case because of vertigo. Twenty-one subjects performed several examinations so that a total number of 257 examinations were carried out (Table 1). All subjects underwent head examinations in the head-first supine position. Various pulse sequences were applied, such as several spin-echo and gradient-echo techniques, EPI, and balanced steady-state free precession. For BOLD fMRI measurements, periscopes for visual stimulation and a button box for motor stimulation were used. In addition, breathing and pulse were monitored with the system respiration sensor and pulse oximeter (Siemens Healthcare). The mean examination duration amounted to 93 minutes.

## Questionnaire (Tübingen)

The questionnaire was the same as that used at Leipzig.

## Data Adaptation and Analysis

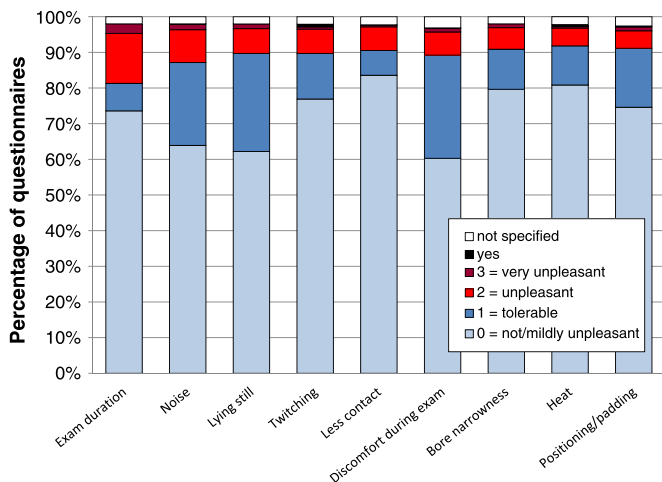
In this multicenter study, data from the different sites have been collected and analyzed retrospectively. No standardized questionnaires and study populations were available. Because of the differences in the questionnaire design concerning the content, amount, and phrasing of the questions and grading scale for the answer options, some information was not included in the final retrospective analysis of the combined multicenter study. Nine questions on the possible causes of discomfort and 4 questions on sensory side effects that were covered by most of the questionnaires (Table 3) were included in the data analysis. The different answer scales were unified by using a 4-point scale (intensity level, 0–3), as applied at Leipzig and Tübingen. The adaptation of the 11-point scale from Essen and the 10-point scale from Heidelberg is shown in Table 1. For the causes of discomfort “examination duration” and “less contact to MR personnel,” Magdeburg and Jülich provided only a 3-point answer option. Their intensity levels were adapted as follows: 0 = examination duration ok/contact good, 2 = examination duration too long/contact sufficient, and 3 = duration far too long/contact very poor. Thus, the best adaptation to the intensity levels from the other MR sites (0 = not unpleasant, 1 = tolerable, 2 = unpleasant, 3 = very unpleasant) could be reached. The negative answers from Magdeburg and Jülich were added to the intensity level 0. The affirmative answers are shown separately as a percentage of subjects.

To assess differences in the sensory side effects for all data of the moving patient table state and all data of the stationary patient table state, the Wilcoxon rank test was used. For comparison between the causes of discomfort and sensory side effects of all questionnaires at 7 T (n = 3147) versus all questionnaires at 9.4 T (n = 310) and for sex analysis, the Mann-Whitney *U* test was applied. The statistical analysis was performed with Statistical Package for the Social Sciences 15.0.1 (Statistical Package for the Social Sciences, Inc, Chicago, IL).

## RESULTS

### General Acceptance of the UHF Examination

No accidents or other undesirable occurrences happened during any examination. None of the subjects were harmfully affected in any way. Of 3467 examinations, 31 were aborted (0.9%). The reasons were nausea (n = 10), claustrophobia (n = 7), vertigo (n = 4), muscle stimulation (n = 3), tussive irritation (n = 2), pain due to previous injury (n = 1), urge to urinate (n = 1), pressure around the head (n = 1), and technical problems (n = 2). However, in 21 of these cases, the subjects were willing to fill out the questionnaire. Hence, a total of 3457 questionnaires could be evaluated (Table 1).



**FIGURE 1.** Causes of discomfort during UHF MRI examinations given in levels of discomfort (scale, 0–3). The data are shown in percentages of all completed questionnaires. For questionnaires without a numerical option for grading (Magdeburg and Jülich), the negative answers were added to level 0 and the affirmative answers were classified as “yes.” The most disturbing cause of discomfort was found for examination duration; in 549 of 3291 (16.7%) questionnaires, duration was stated as being at least unpleasant.

All sites except Magdeburg included the question “Did you feel discomfort during the examination,” whereby Essen, Heidelberg, Leipzig, and Tübingen differentiated the degree of discomfort by (slightly different) gradings and Jülich used a yes/no option. In 60.3% (2016/3344 questionnaires, excluding the 113 questionnaires from Magdeburg) of the completed questionnaires, the examinations were scored as being not unpleasant; in 29.0% (968/3344) of the completed questionnaires, the examination was scored as being tolerable; in 6.5% (217/3344) of the questionnaires, the subjects felt discomfort; and in 1.0% (33/3344) of the questionnaires, the subjects felt strong discomfort during the examination. In 9% (5/53) of the questionnaires from Jülich, discomfort was affirmed.

The questionnaires of Essen, Heidelberg, Magdeburg, Leipzig, and Tübingen included a question about the willingness to undergo a similar examination in the future. In 96.6% (3289/3404) of these questionnaires, subjects would be willing to undergo a future UHF examination; in 0.91% (31/3404) of the questionnaires, subjects were unwilling to undergo another examination for any reason; and in 2.5% (84/3404) of the questionnaires, subjects did not answer this question. Essen and Heidelberg (n = 972) differentiated the positive response option between “I am willing to undergo another examination to support clinical research” and “...only for personal medical necessity”; 79.2% (771/972) of the subjects were willing to support research again and 12.9% (125/972) of the subjects would undergo another examination only for personal medical necessity.

**Sources of Discomfort**

Figure 1 presents the sources of discomfort during both 7- and 9.4-T MR examination. Given are the levels of discomfort, with the sources ranked in order of their score for the highest level 3 = “very unpleasant.” Level 3 was indicated most often for examination duration (88/3291\*, 2.7%) and acoustic noise (53/3344†, 1.6%). The

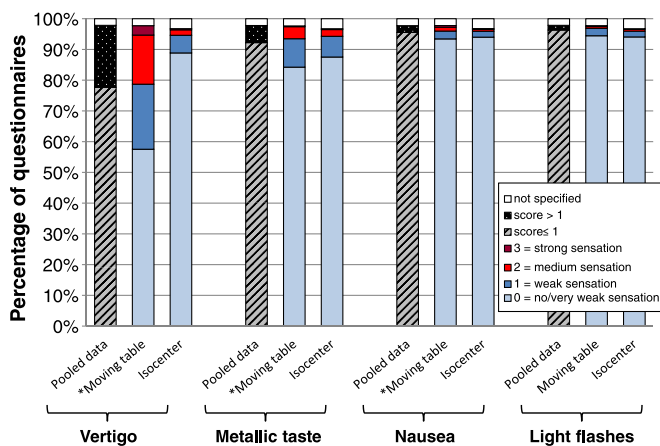
\*n = 3291 includes all questionnaires from Essen, Heidelberg, Leipzig, and Tübingen.  
 †n = 3344 includes all questionnaires from Essen, Heidelberg, Leipzig, Jülich, and Tübingen.

pooled results of levels 2 and 3 and the positive answers from Magdeburg and Jülich again identified examination duration (549/3291, 16.7%) and acoustic noise (363/3344, 10.9%) as being the most frequent causes of discomfort. Table 3 presents the mean values of the scores and the percentages of scores greater than 1 for all sources of discomfort at the different MR sites.

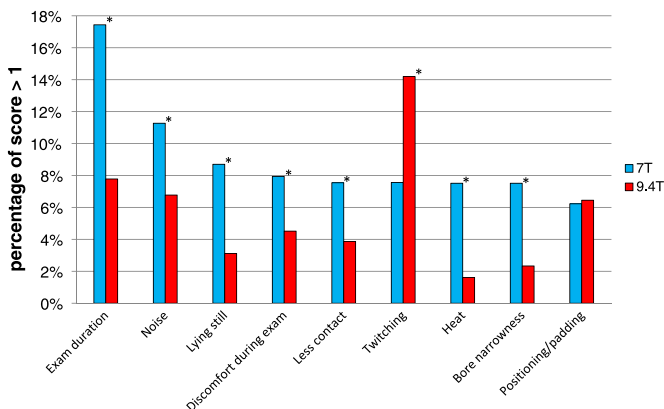
**Sensory Side Effects**

Figure 2 shows the individual sensory side effects given in intensity levels (0 = no/very weak sensation, 1 = weak sensation, 2 = medium sensation, and 3 = strong sensation) (see also Table 3). By far the most pronounced sensation was vertigo. The pooled results of intensity levels 2 and 3 and the positive answers from Magdeburg and Jülich add up to 20.2% of the completed questionnaires (697/3457) where subjects stated at least a medium sensation of vertigo. In 5.6% (193/3457) of the questionnaires, a metallic taste was experienced; in 2.2% (72/3291) of the questionnaires, subjects felt nausea; and in 1.6% (52/3457) of the questionnaires, subjects experienced light flashes with a grade higher than intensity level 1. The questionnaires from Essen, Heidelberg, Leipzig, and Tübingen differentiated between a sensation during the movement into and out of the magnet bore on the patient table and while lying on the stationary patient table in the isocenter. The aforementioned values resulted from the maximum intensity level for either moving state or stationary state for the corresponding MR sites.

Individual sensory side effects differed between stationary and moving patient table (Fig. 2, Table 3). This was, by far, most pronounced for vertigo (*P* < 0.001). In 19.1% (627/3291) of the questionnaires, the subjects scored vertigo in the case of the moving table higher than level 1 (score 3, n = 101/3291, 3.1%). In contrast, only in 2.2% (71/3291) of the completed questionnaires did subjects score vertigo for the stationary table with more than level 1 (score 3,



**FIGURE 2.** Individual sensory side effects experienced during MR examination given in intensity levels (score, 0–3). First bar of each side effect: pooled percentage of completed questionnaires where subjects stated (1) no or weak sensation (score ≤ 1) and (2) either a medium or a strong sensation (score > 1) plus the affirmative answers from questionnaires from Magdeburg and Jülich without an option for numerical grading. Second and third bars: sensations subdivided for moving patient table and for static isocenter position (subjects from Essen, Heidelberg, Leipzig, and Tübingen). By far, the most often reported sensation was found to be vertigo, where in 3.1% of the questionnaires, a strong sensation (score, 3) was experienced. Vertigo, metallic taste, and nausea were rated significantly worse for the moving patient table compared with the isocenter position (\**P* < 0.05).



**FIGURE 3.** Percentage of completed questionnaires where subjects experienced causes of discomfort graded higher than 1 (levels of discomfort: 0 = not/mildly unpleasant, 1 = tolerable, 2 = unpleasant, 3 = very unpleasant) subdivided for the 7- and 9.4-T MR examinations. Significant differences between 7- and 9.4-T examinations are indicated [ $*P < 0.05$ ; note:  $n(7\text{ T}) = 3149$ ,  $n(9.4\text{ T}) = 310$ ].

$n = 13/3291$ , 0.4%). A significant but less pronounced difference concerned metallic taste ( $P < 0.05$ ). In 4.2% (137/3291) of the questionnaires, subjects graded metallic taste during movement higher than level 1 versus 2.5% (81/3291) in the isocenter position; no significant difference was found for score 3:  $n = 8$  (0.2%) for moving table and  $n = 9$  (0.3%) for isocenter position. Also, nausea showed a significant difference for grades higher than 1 ( $P < 0.05$ ): 1.8% (59/3291) of the completed questionnaires during patient table movement versus 0.9% (29/3291) in the isocenter position. Nausea was graded more often with score 3 than metallic taste was:  $n = 18$  (0.6%) for moving table and  $n = 10$  (0.3%) for the isocenter position. The score for light flashes did not show any significant differences between the 2 scenarios. Table 3 presents the mean score values of all sensations in general, during movement, and in the isocenter position.

**7 T Versus 9.4 T**

The results for the causes of discomfort and sensory side effects were compared between the 7-T examinations (Essen, Heidelberg, Magdeburg, and Leipzig;  $n = 3147$ ) and the 9.4-T examinations (Jülich and Tübingen;  $n = 310$ ). Because the number of questionnaires differs extremely between the 2 field strengths, an interpretation of the results must be made with caution. In addition, only examinations on healthy, mainly young, volunteers were performed at 9.4 T (cf. Table 1). Figure 3 displays the percentage of completed questionnaires where subjects graded the different causes of discomfort as higher than level 1 for both 7- and 9.4-T MR examinations. The most pronounced causes of discomfort at 7 T were examination duration (score  $>1$ , 529/3034<sup>‡</sup>, 17.4%) and acoustic noise (score  $>1$ , 342/3034, 11.3%), which both yielded discomfort at 9.4 T as well but were less pronounced (examination duration: score  $>1$ , 20/257<sup>§</sup>, 7.8%; noise: score  $>1$ , 21/310, 6.8%). Instead, high gradings for twitching (score  $>1$ , 44/310, 14.2%) and positioning/padding (score  $>1$ , 20/310, 6.5%) resulted at 9.4 T. Except for these 2 issues, all other causes of discomfort were graded with a significantly higher score at 7 T ( $P < 0.02$ ). The general discomfort was rated as higher than level 1 in nearly twice the percentage of questionnaires at 7 T than at 9.4 T (7 T, 241/3034, 7.9%; 9.4 T, 14/310, 4.5%;  $P < 0.02$ ).

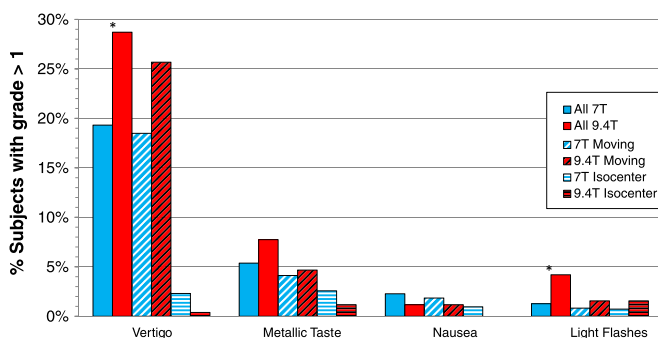
<sup>‡</sup> $n = 3034$ : all 7-T questionnaires except from Magdeburg.  
<sup>§</sup> $n = 257$ : only 9.4-T questionnaires from Jülich.

Vertigo was rated as higher than level 1 by a factor of 1.5 more often at 9.4 T compared with 7 T (score  $>1$ : 7 T, 608/3147, 19.3%; 9.4 T, 89/310, 28.7%) ( $P < 0.001$ , Fig. 4). If all questionnaires where subjects stated even mild perception of vertigo are added (ie, score  $>0$ ), the difference is even more pronounced: 7 T, 1187/3147 (37.7%); 9.4 T, 186/310 (60.0%). Furthermore, subjects who underwent a 9.4-T examination rated light flashes (score  $>1$ : 7 T, 39/3147, 1.2%; 9.4 T, 13/310, 4.2%) significantly higher ( $P < 0.001$ ) than did subjects who were examined at 7 T. Also, metallic taste was reported more often at 9.4 T (score  $>1$ : 7 T, 196/3147, 5.4%; 9.4 T, 24/310, 7.7%); however, there was no statistically significant difference. The percentage of questionnaires where subjects reported sensory side effects during patient table movement in comparison with the isocenter position was elevated in a similar manner for both 7- and 9.4-T examinations.

**Differences Between MR Sites**

Table 3 shows the mean score values and percentages with score higher than 1 for the causes of discomfort and for the sensory side effects for all MR sites separately. For Essen and Heidelberg, examination duration and acoustic noise were the most often stated reasons of discomfort. For all other sites, the most common cause of discomfort was vertigo. At Essen and Heidelberg, mean scores ranged between 0.4 and 1.2 for the causes of discomfort. In contrast, for Leipzig and Tübingen, the highest mean scores were 0.3 and 0.5, respectively. Questionnaires from Magdeburg showed similar results for twitching and heat as at Heidelberg and Essen. The results from Jülich revealed high values for positioning/padding, general discomfort, and twitching and therewith were similar to Essen and Heidelberg; acoustic noise, contact, and heat, however, yielded lower values compared with other sites.

For all sites, vertigo was the most frequently stated sensory side effect. The questionnaires from Leipzig showed, in general, lower mean score values for all sensations. The highest values were reached at Jülich, with a percentage of 43% for vertigo, 23% for metallic taste, and 15% for light flashes.



**FIGURE 4.** Percentage of completed questionnaires where subjects experienced individual sensations graded higher than 1 (intensity level: 0 = no/very weak sensation, 1 = weak sensation, 2 = medium sensation, 3 = strong sensation) subdivided for 7- and 9.4-T MR examinations. In the first and second bars, results from all 7- and all 9.4-T examinations are shown, respectively [ $*P < 0.05$  for comparison of “all 7 T” vs “all 9.4 T”; note:  $n(7\text{ T}) = 3149$ ,  $n(9.4\text{ T}) = 310$ ]. In the third and fourth bars, the results for the moving patient table are presented for 7- and 9.4-T examinations, respectively. The fifth and sixth bars represent the sensations while lying in the static isocenter position. Questionnaires without differentiation of moving/static state only appear in the respective “all 7 T/9.4 T” bar.

### Multiple Examinations

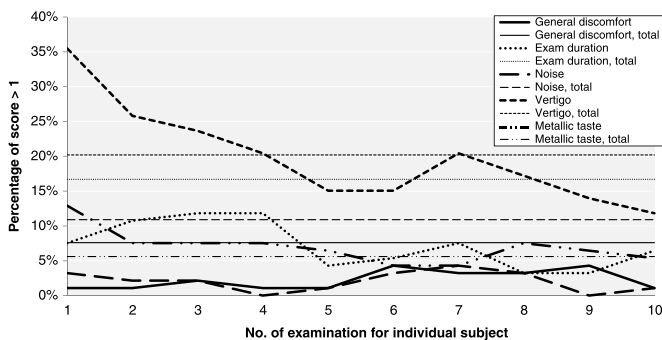
At Magdeburg, Leipzig, and Tübingen, many subjects performed more than 1 examination and completed the questionnaire after each examination. To evaluate the possible influence of these multiple examinations on the overall causes of discomfort and sensations, the results of all subjects who performed at least 10 examinations were analyzed in detail (number of subjects = 93; number of analyzed questionnaires = 930). Figure 5 displays the most often stated causes of discomfort and sensory side effects according to Table 3 (examination duration, noise, general vertigo, and general metallic taste; additionally general discomfort) as a function of the examination number per individual subject. The intensity level of general vertigo decreases with the increasing number of examination repetitions: After the first examination, 33 of 93 subjects (35.5%) stated vertigo with intensity level higher than 1, and after the tenth examination, only 11 subjects (11.8%) stated vertigo higher than score 1. For all other sensations and causes of discomfort, no relevant deviations over the increasing number of examination repetitions could be detected. However, the number of subjects who stated the causes of discomfort and sensations was, in some cases, very small (eg, a maximum of 4 subjects graded general discomfort and acoustic noise higher than score 1).

### Sex

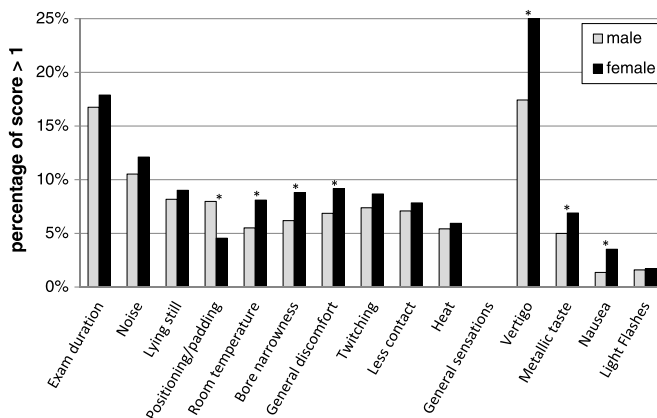
Figure 6 shows the distribution of the questionnaires completed by men and women regarding causes of discomfort and sensations. In general, female subjects rated the causes of discomfort worse than male subjects did and seemed to be more sensitive to sensory side effects ( $P < 0.05$ ; general discomfort, room temperature, bore narrowness, vertigo, metallic taste, nausea). The highest difference between men and women resulted for vertigo (score >1: men, 328/1882, 17.4%; women, 317/1465, 25.3%) and nausea (score >1: men, 24/1752, 1.4%; women: 50/1420, 3.5%). Male subjects were significantly more irritated by the positioning and padding on the patient table ( $P < 0.05$ ).

### Age and Healthy Volunteers Versus Subjects With Known Pathologies

Figure 7 depicts the comparison between young healthy volunteers up to the age of 30 years (mean age, 25 years), healthy

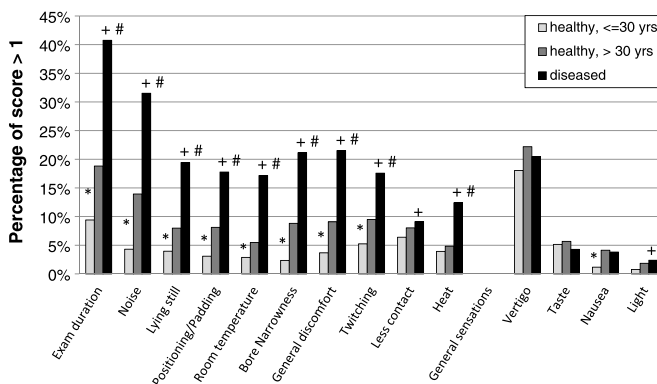


**FIGURE 5.** Analysis of questionnaires after multiple examinations: General discomfort, examination duration, noise, general vertigo, and general metallic taste are shown in percentages of subjects who graded with more than intensity level 1 (fat lines). The results are given for the increasing number of examinations per subject (up to 9 repetitions). Only subjects who performed at least 10 examinations (N = 93) were included. For comparison, the mean percentage of all questionnaires from all sites is shown with the fine lines (cf. Table 3).



**FIGURE 6.** Comparison of causes of discomfort and general sensations (including both during movement on the patient table and lying still in the isocenter) between men (number of questionnaires = 1882) and women (number of questionnaires = 1465). The results are given in percentages of questionnaires where the subjects graded with more than intensity level 1. In general, women rated the causes of discomfort and sensations worse than men did, except for positioning/padding ( $*P < 0.05$ ).

volunteers older than 30 years (mean age, 40 years), and subjects with known diseases (mean age, 48 years). All causes of discomfort and sensations are shown in percentage of questionnaires where subjects rated the corresponding causes of discomfort at least as “unpleasant” and the sensory side effects at least with “medium sensation.” Significantly higher gradings for all causes of discomfort except “less contact to MR personnel” were observed for the



**FIGURE 7.** Comparison of causes of discomfort and general sensations (including both during movement on the patient table and lying still in the isocenter) between young healthy volunteers up to age 30 years (number of questionnaires = 2354), healthy volunteers older than 30 years (number of questionnaires = 384), and subjects with known diseases (number of questionnaires = 431). The results are given in percentages of questionnaires where the subjects graded with more than intensity level 1. Diseased subjects were generally more irritated by the nonmagnetic-field-dependent causes of discomfort, such as examination duration and noise, than healthy volunteers were.  $*P < 0.05$ , young vs older volunteers;  $+P < 0.05$ , young volunteers vs diseased subjects;  $\#P < 0.05$ , older volunteers vs diseased subjects.



subjects with known diseases compared with the healthy volunteers. Highest values were reached for examination duration (score >1, 171/481, 39.7%, questionnaires from subjects with known diseases; 58/384, 15.2%, questionnaires from older healthy volunteers; and 208/2354, 8.8%, questionnaires from younger healthy volunteers). The comparison between younger and older healthy volunteers showed that older subjects were more irritated by all causes of discomfort, except contact with the MR personnel. Furthermore, Figure 7 shows that for the magnetic-field-dependent sensory side effects, the differences between the 3 groups of subjects were much less pronounced than for the magnetic-field-independent causes of discomfort.

## DISCUSSION

Although the number of UHF MR whole-body scanners worldwide is continuously increasing, publications on subjective perception of discomfort during UHF examinations are rare. Only the data of Theysohn et al<sup>27</sup> and later continued by Heilmaier et al<sup>28</sup> give detailed results about general acceptance and discomfort during UHF MR examinations. Their conclusion was that it is essential to collect more data from UHF study participants and that monitoring of the sources of discomfort should be continued at as many sites as possible. Versluis et al<sup>26</sup> published data on subjective sensations and the overall experience from 101 healthy young volunteers during 7-T examinations. Here, we present the first multicenter study on subjective acceptance of UHF examinations, where 6 different sites participated, with a total number of 3457 questionnaires. Furthermore, we performed additional analysis that encompasses the effects of multiple examinations and a comparison between healthy and diseased subjects. In general, we found a high acceptance of UHF examinations, and only 7.6% felt discomfort during the examination, which is in accordance with the findings from Theysohn et al, Heilmaier et al, and Versluis et al. This high acceptance leads to the assumption that UHF MRI would be tolerated as a diagnostic tool in clinical practice.

Examination duration was the most pronounced cause of discomfort and could have influenced other reasons of discomfort (eg, lying still, positioning/padding, bore narrowness). This is explained, at least in part, by long scanning sessions (cf. Table 1) resulting from extensive study designs that are typical in studies motivated by research as performed here instead of more focused clinical examinations for diagnostic purposes, which would be less time consuming. In addition, work related to optimization of the imaging protocols, examination handling, and long shimming processes could have prolonged the examination durations. Our data at 1 specific site showed a tendency of less frequent statements of “general discomfort” in later examinations as compared with earlier examinations. This might point to a beneficial effect from improvement of the examination procedure due to gained experience, or it might be related to subject familiarization.

By far the most pronounced individual sensory side effect was vertigo, which confirms findings from previous studies on sensory side effects induced by high static magnetic fields.<sup>18,26,32,33</sup> Vertigo, metallic taste, and nausea were felt significantly more often during movement of the patient table than in the stationary isocenter position, although all MR sites respected the recommendations from International Commission on Non-Ionizing Radiation Protection<sup>13</sup> and moved the patient table very slowly through the position of maximum ( $B_0 \times dB_0/dz$ ) at the magnet's bore entrance.

The comparison between 7 and 9.4 T should be interpreted very carefully because of the different study populations and number of questionnaires. The reason for the apparent less uncomfortable 9.4-T examinations with respect to almost all causes of discomfort (cf. Fig. 3) might be revealed by the different results between the MR sites, which are discussed in detail below.

Vertigo and light flashes were significantly more pronounced at 9.4 T compared with 7 T, which further indicates effects triggered by induced currents in the body that increase with  $B_0$ .<sup>25,32,34</sup> However, large differences were found between the MR sites regarding the causes of discomfort. Therefore, it is hard to distinguish whether the different results at 9.4 T versus 7 T are a consequence of low-frequency magnetic fields or of different questionnaire designs, study populations, or subject performance. Although one has to be careful in interpreting the significances, the field strength comparison identifies a possible tendency of increasing sensory side effects with the static magnetic field.

Comparing the different sites, it is notable that all values from Essen, Heidelberg, and Magdeburg are highly elevated compared with those from Leipzig and Tübingen. This might have different reasons. First, the design of the questionnaires from Essen and Heidelberg differs from that of Leipzig and Tübingen. The adaptation of the 11-point scale from Essen and 10-point scale from Heidelberg to the 4-point scale (Leipzig and Tübingen) could have influenced the result. Second, more than half of the subjects from Essen and Heidelberg had known pathologies, and many of them may have experienced poor general constitution because of, for example, advanced tumor diseases. As observed in the analysis of healthy versus diseased subjects (Fig. 7), these subjects rated the comfort of the UHF MR examination considerably worse than healthy volunteers did. The diseased subjects were especially irritated by the examination duration. This could also be an explanation for the unexpected observation that at the sites with the longest mean examination duration (Jülich, 93 minutes; Leipzig, 80 minutes; cf. Tables 1 and 3), the lowest mean discomfort score values for examination duration were obtained. In addition, at Essen and Heidelberg, the subjects were, in general, older than subjects at Magdeburg, Leipzig, Jülich, and Tübingen (cf. Table 1). In Figure 7, we show that older volunteers tolerated the MR examination less well than younger volunteers did, and thus, the differing age distributions at the different sites additionally affected the results. A further limitation in comparing the different sites is that at Magdeburg, Leipzig, and Tübingen, volunteers were examined several times and they filled out the questionnaire after each scan. Typical causes of discomfort such as acoustic noise, bore narrowness, lying still, and general discomfort might be less pronounced because of familiarization. However, the analysis of the multiple examinations for the causes of discomfort (cf. Fig. 5) did not reveal a significant improvement in the subjects' comfort over the increasing number of examinations per individual subject. Only the influence on vertigo seems to be more crucial than for other causes of discomfort. Subjects who performed several examinations felt less often dizzy than did subjects during their first examination, which might have influenced the differences between sites with multiple examinations and sites that performed only 1 examination per subject. Furthermore, although all sites tried to standardize subject care, the subjects might not have received the same information regarding side effects, which could have sensitized them to certain effects. This also concerns the manual movement of the patient table. Despite overall standardized subject preparation, the table velocity was not controlled and was based only on the individual subjective perception of the MR personnel. In addition, the unbalanced sex ratio of the participating subjects for Magdeburg, Jülich, and Tübingen (cf. Table 1) could be a limitation because we found that female subjects rated higher scores for field-related sensations than men did (cf. Fig. 6). According to a study from Chaplin et al,<sup>35</sup> women and men respond to stress differently, with women experiencing greater anxiety than men do, although Theysohn et al<sup>27</sup> could not find any significant sex difference during 7-T MR examinations. The stronger vertigo experienced by female subjects could have influenced other causes of discomfort such as bore narrowness or general discomfort. In addition, the different head coils could have influenced the results because a tighter coil may cause more discomfort. All head coils used had very similar diameters, but the 24-channel/

32-channel receive head coil (7 T) and the custom-built 16-channel transmission/32-channel receive array from Tübingen (9.4 T) are about 8 cm smaller than the other coils (cf. Table 2). Because the 24-channel/32-channel coil was used at all 7-T sites, the small coil size might explain the more uncomfortable 7-T examinations compared with 9.4 T, especially for bore narrowness (cf. Fig. 3). The last point to discuss regarding the large differences between the sites is the unequal number of questionnaires. Leipzig collected more questionnaires than all other sites together. Therefore, the total mean values of the causes of discomfort and sensations were determined, to a great extent, by the results from Leipzig. However, we think it is important to evaluate and present these data comprehensively, as these represent the combined state of experience with UHF MRI in Germany.

Because of the aforementioned limitations concerning the differences between the MR sites, we propose a consistent and simple questionnaire for future UHF examinations (see text documents, Supplemental Digital Content 1, <http://links.lww.com/RLI/A143>, which contains the questionnaire in English; and Supplemental Digital Content 2, <http://links.lww.com/RLI/A144>, which contains the questionnaire in German). The questionnaire consists of 12 questions concerning causes of discomfort and 7 questions about sensory side effects during patient table movement and while lying still in the isocenter of the MR system's magnet. Besides the presented causes of discomfort, we suggest adding feeling of numbness and tiredness, which were included by Leipzig and Tübingen and resulted in relatively high subject percentages compared with the other sources of discomfort at these MR sites (numbness, 5.4%; tiredness, 3.9%; both percentages of score >1). Furthermore, we have added fear, headache, and tachycardia as sensory side effects to the new questionnaire because the data from Essen and Heidelberg show relatively high values compared with other sensations (fear during movement, 4.3%; tachycardia during movement, 3.2%; headache in the isocenter position, 6.9%; all percentages of score >1). All causes of discomfort and sensations should be stated on a 4-point scale referring to the intensity level. This underlines the importance of determining whether a cause of discomfort/sensation is only very mildly noticeable or definitively strong; thus, an intensity level rating is desirable. On the other hand, because of feedback from Heidelberg, where both subjects and examiners stated that rating the decision on a 10-point scale was too complicated and time consuming, we chose the more simple scale.

In conclusion, this multicenter study shows a high general subjective acceptance of UHF MR examinations, where in 96% of the completed questionnaires, the subjects would be willing to undergo another UHF MR procedure. The most common reasons given for feeling discomfort during UHF examinations were vertigo while moving into or out from the magnet bore, followed by the duration of the examination. However, we found large differences among the 6 sites, with discomfort being identified much less often at some sites. There is evidence that typical sensations such as vertigo and magnetophosphenes occur more often at 9.4 T compared with 7 T, although more 9.4-T data and a consistent questionnaire design are required to confirm this supposition. We propose that all UHF MR sites use the standardized questionnaire in the supplemental material for subjective perception monitoring or include the proposed questions within their own questionnaires. A more consistent data ascertainment and deeper information about the acceptance of UHF examinations and short-term effects of the strong static magnetic field  $B_0$  and  $dB_0/dt$  could thus be achieved; this information would be particularly relevant given the continuously increasing number of human MR systems with magnetic fields of 7 T or above.

#### ACKNOWLEDGMENT

The authors thank H. Hetzheim, J. Groebner, B. Dillenberger, and C. Kindtner for data collection in Heidelberg; the many

researchers involved in data collection in Essen; M. Dobrowolny and A. Fügner for data collection in Magdeburg; M. Reske and D. Krug for data collection in Tübingen; and D. Wilfling and E. Wladimirow for experimental support in Leipzig. Tübingen acknowledges financial support through the German ministry of education and research under grant number 13N9121.

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