10

Subject tolerance of 7 Tesla MRI examinations

M.J. Versluis
W.M. Teeuwisse
H.E. Kan
M.A. van Buchem
A.G. Webb
M.J. van Osch

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ABSTRACT

Purpose: To determine the subjective experiences and the sources of discomfort for subjects undergoing 7 Tesla MRI examinations on a whole-body 7 Tesla system within a hospital setting

Materials and Methods: A post-scan survey was filled out by 101 healthy subjects who participated in a 7 Tesla examination. All participants answered questions regarding different potential sensations of discomfort including dizziness, claustrophobia, and scanner noise.

Results: Dizziness was reported most frequently with 34% of subjects experiencing dizziness while moving into the scanner and 30% while moving out of the magnet. Scanner noise was also frequently mentioned as uncomfortable (33% of the subjects). In 11% of the cases a metallic taste was reported. The overall experience was rated by 3% as unpleasant, 51% as neutral and 46% as pleasant.

Conclusion: The reported side effects are larger than previously reported for lower field strengths. However, overall 7 Tesla examinations are well tolerated, with only 3% of subjects rating it as unpleasant. These results agree well with previous in-depth studies, and provide further evidence that 7 Tesla MRI would be accepted by patients in clinical practice.

INTRODUCTION

There has been a rapid increase in the number of whole body 7 Tesla MRI scanners in research centers and hospitals worldwide; at the end of 2011 more than 30 systems were in operation. For 7 Tesla MRI to fulfill the promise of increased spatial resolution and increased sensitivity for the identification of pathologies in the clinical setting, it is important to assess how well examinations are tolerated by subjects and what adverse side effects, if any, are reported and whether they can be easily mitigated. The subjective perception of 7 Tesla examinations is important for local institutional review board (IRB) approval and for acceptance of 7 Tesla MRI as a true "medical device" by the regulatory bodies as opposed to the "investigational status" it has currently.

A number of studies have been performed on high field systems that have examined the possible effects of MRI on human subjects. Earlier studies at different field strengths of up to 9.4 Tesla have shown no effect of the static magnetic field on vital signs, such as blood pressure and heart rate (1–3) and very limited (2, 4) or negligible effects (5, 6) on cognitive function, such as short term memory have been found. A small effect on eye-hand coordination and the visual sensory domain was reported in the stray field of a 7 Tesla magnet, where subjects experienced a maximum of 1.6 Tesla (7). Perceived side effects occur most commonly when the subject moves through a high magnetic field gradient, with a metallic taste reported in 50% of subjects who shook their heads in the stray field of a 7 Tesla magnet (8). Vertigo can be induced by the induction of currents through the vestibular hair cells (9), but most reported side effects are acute and disappear rapidly after the exposure ended (10) and the United States Food and Drug Administration (FDA) has therefore classified MR systems of up to 8 Tesla to be non-significant risk devices for subjects above one month of age (11).

There have been two previous studies performed in subjects undergoing a 7 Tesla examination by the Essen group on a whole-body Siemens system to assess the subjective experience of a large number of both healthy volunteers and patients (12, 13). Their results indicated that feelings of dizziness and general discomfort were more pronounced at 7 Tesla than at 1.5 Tesla, but that overall the general acceptance was high with only ~12% of subjects rating the experience as unpleasant. Since results from subjects undergoing a 7 Tesla MRI exam from only one geographical site and one specific magnet/vendor configuration have so far been reported, it is important to assess whether these findings are similar at other sites and on scanners of other vendors for general acceptance of clinical 7 Tesla MRI. Specifically we report

from experiences on a Philips 7 Tesla scanner which has a slightly smaller diameter than the Siemens scanner in Essen, and which is also geographically located in a clinical hospital environment. Given the somewhat subjective nature of subjects reactions, one other important difference is that the siting-plan of the Philips scanners indirectly "obscures" the long length of the scanner bore (compared to 1.5 and 3 Tesla scanners) by having plastic side-planes which connect to the inside of the shielded room, in contrast to general siting for Siemens systems in which the volunteer can see the entire magnet bore. However the result on the perception of subjects is not clear.

METHODS

101 healthy subjects with mean age of 27 years (range is 18 – 57 years) underwent a 7 Tesla MRI examination on a human Philips Achieva scanner with a clear bore diameter of 58 cm and length of 340 cm. The diameter of 58 cm is slightly smaller than the 59.5 cm for the Siemens scanner used in previous studies: although this difference is small it is likely to have some effect on the experience of patient comfort. Many different scanning protocols were used, incorporating both imaging and spectroscopy, with individual scans ranging in duration from less than a minute to approximately 10 minutes. The types of sequences that were performed have not been recorded, but it has been estimated based on vendor supplied reports that highest noise levels are around 105 dB. In all cases the total scanning period was limited to one hour. All brain examinations were performed using a close fitting 16 channel Nova Medical (Wilmington, MA, USA) phased array receive-coil with a diameter of 29.2 cm and length of 26 cm, other examinations of the knee and calf muscle were performed using various custom built coils. For examinations of the calf muscle and knee, subjects were positioned feet first in the magnet, for examinations of the brain, subjects were head first in the magnet. Subjects were moved manually inside and outside the scanner bore at a constant pace of approximately 7 cm/s. No attempt was made to reduce the table speed in the vicinity of the highest gradient of the magnetic field. Noise protection was provided (3M Ear Classic) with a reported average noise reduction of 28 dB. When space within the coil allowed a custom adapted version of the manufacturer provided headphone was used for additional protection.

In conjunction with our local medical ethics committee a questionnaire was created to assess the experience of the participants in 7 Tesla MRI studies. Participants were recruited using advertisements in public spaces of our hospital and near the lecture rooms for medical students, and received a small compensation in the form of a gift certificate. Similar to examinations per-

formed on the clinical 1.5 Tesla and 3 Tesla scanners in our hospital, before scanning all subjects were informed of possible side-effects: claustrophobia, dizziness, metallic taste, noise and possible muscle twitching. No mention was made that these effects might be more intense than experienced at the lower field systems.

Immediately after the examination was finished the subjects were asked to fill in the questionnaire (see table 1) under supervision of a researcher to ensure accurate understanding of the questions. All questions were answered on the scale: yes, a little, or no except for the final question (overall experience), which was rated: unpleasant, neutral, or pleasant and the open question regarding additional comments of the subjects. The total duration of the examination was also recorded. Differences in side effects between subjects that were head first in the scanner versus feet first were addressed with a $\chi 2$ test (SPSS 17.0, Chicago, US).

Because the primary purpose of the questionnaire was to comply with IRB regulations, additional details regarding scanning protocol, weight and height of subjects and history of previous MRI examinations were not recorded.

RESULTS

The responses to the questionnaire are summarized in figure 1; the findings are shown in descending order according to the number of participants answering yes, except for the last two questions, which were answered mostly positive. The total duration of the examination was approximately one hour (58 ± 8 minutes). The three most frequently reported negative findings (answers yes and a little) were, in descending order, dizziness moving in to the magnet (34%), scanner noise (33%) and dizziness moving out of the magnet (30%). 11% of subjects reported a metallic taste during the examination. Dizziness during scanning was mentioned in a similar number of cases (14%), which was significantly less frequent compared to dizziness while moving into or out from the magnet. This is an indication that both effects are likely to be caused by moving through the strong static magnetic field gradients, as also found in the previous studies (8, 9). Out of the 101 subjects included in this survey only two could not undergo the examination due to severe claustrophobia. One subject reported seeing light flashes during the first 10 minutes inside the scanner and one subject reported sensations of peripheral nerve stimulation. These remarks were reported in the additional comments section of the questionnaire and were not directly targeted as such. Of all cases, 78% were brain examinations, 9% knee examinations and 3% were examinations of the calf muscle, in 10% of the cases it was not possible to re-

trieve retrospectively what body part was imaged. A statistical trend towards more remarks of dizziness was reported by subjects that were head first in the scanner when they were moved outside the bore ($\chi 2$ test, $p = 0.054$). No other differences were found. Whether subjects were well informed prior and during the examination was answered with yes by almost all subjects (98% and 97%, respectively). The large majority of the participants rated the examination as pleasant or neutral, with only 3% of subjects rating the examination as unpleasant, 51% as neutral and 46% as pleasant.

Table 1: Questionnaire
Did you experience dizziness when moving in the scanner?
Did you experience dizziness during scanning?
Did you experience dizziness when moving out the scanner?
Did you experience nausea during the examination?
Did you experience a metallic taste during the examination?
Was it too cold during the examination?
Was it too warm during the examination?
Were you feeling claustrophobic?
Did you suffer from the scanner noise?
Are there any additional comments?
What was your overall experience?
Were you informed well prior to the examination?
Were you informed well during the examination?

All questions were answered on the scale: yes, a little, no except for the last question (overall experience), which was rated: unpleasant, neutral, pleasant and the open question about additional comments.

DISCUSSION

The most important finding of this short survey is that 7 Tesla examinations in a hospital setting were tolerated well by healthy subjects. The most common experience was dizziness while moving inside the scanner bore, which was mentioned more frequently than previously reported at 1.5 Tesla (12), therefore it might be advantageous to inform subjects when they are being moved into the scanner of possible feelings of dizziness. In most cases dizziness was reported to disappear rapidly once inside the scanner. It has been hypothesized that the dizziness during movement is induced by magnetic susceptibility differences between the vestibular organs and the surrounding

fluid and induced currents acting directly on the vestibular hair cells (9).

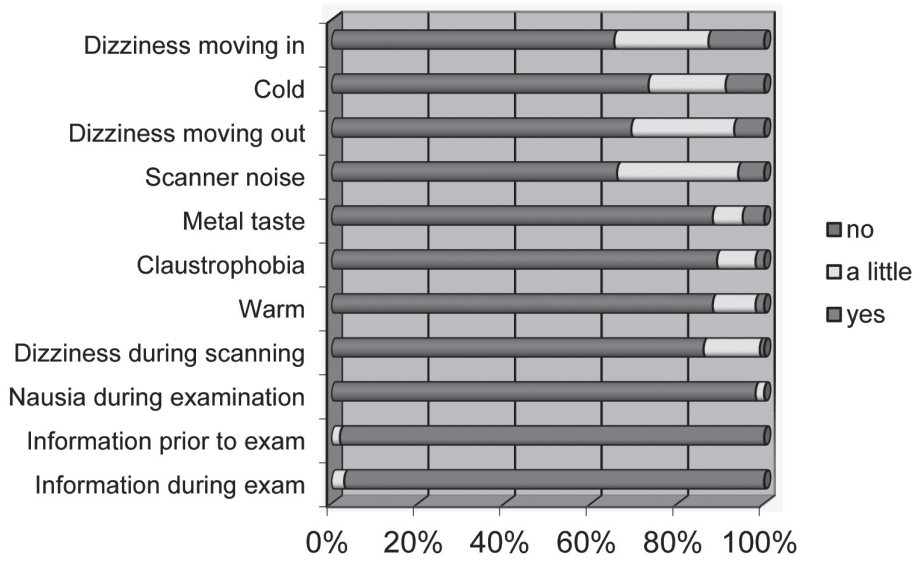

Figure 1: Results of the questions listed in table 1 in 101 subjects.
The most mentioned unpleasant remarks were dizziness when moving in and out of the magnet and the amount of scanner noise.

In terms of direct comparison of the results of this survey compared to the two previous studies in Essen, there is a strong general agreement for many of the either neutral or negative effects. For example, in Theyson et al. (13) approximately 25% of the subjects scanned at 7 Tesla reported dizziness during manual table movement, while our findings show slightly larger numbers (34% and 30% while moving in to and out from the scanner, respectively). More people reported a definite (rather than slight) sense of dizziness moving into the magnet as opposed to moving out, and this can be explained both by initial trepidation at the start of a scan as compared to a more relaxed feeling at the end of the scan in terms of heightened awareness to possible side-effects. Because the table had to be moved manually at the time of this study by different operators, there were variations in table speed between subjects, resulting in corresponding differences in sensations of dizziness. The larger number of subjects reporting dizziness when moving out of the scanner when they were positioned head first in the scanner compared to feet first is likely to be caused by movement of the head through the highest magnetic field gradient. However it must be noted that the number exams performed outside the brain was very limited (12%). Scanner noise is also mentioned frequently as unpleasant, which for studies

of the head could be explained by the limited space available for noise protection. The small size of the receive head coil frequently prevented the use of head phones in addition to ear plugs. This was especially the case for subjects with larger head sizes. A metallic taste was reported by 11% of the subjects, which is more than twice as frequent as previously reported (13) and is thought to be induced by moving through the static magnetic field (8). In contrast to previous studies, the length of the examination was not mentioned specifically by any volunteer as being a problem. There can be several reasons explaining this difference. First, the subjects were explicitly told that the maximum scan duration allowed by our IRB was one hour. Second, throughout the examination the subject was told how long each scan would take (shortest ~1 minute, longest ~10 minutes), and asked after every scan if they were comfortable. Thus full information was available to the subject throughout the examination – in accordance with recommended clinical procedures. A potential bias in the subject recruitment can exist because it was not recorded whether subjects had undergone any previous MRI examinations at lower field strengths, which can influence reported numbers on claustrophobia and other side effects.

Previous literature studies have focused on the effects of (moving through) the static magnetic field and have reported relatively mild effects in line with these findings. The most frequently mentioned effects are caused by moving through the magnetic field, similar to subjects being positioned in the scanner bore in this study and include a metallic taste, dizziness or concentration problems (2, 8–10). However these studies did not include an actual MRI examination, which is likely to influence the overall perception of possible side effects. Operating conditions, such as matching table speed to the position of the head within the magnetic field gradient (slowest speed through the highest gradient) could be adapted to minimize dizziness.

Overall the 7 Tesla MRI examinations were tolerated well, which is confirmed by only 3% of subjects rating the examination as unpleasant. Claustrophobia was only mentioned in a very small number of cases and resulted in only two subjects not being able to participate.

In conclusion, this report supports previous literature in showing that in general 7 Tesla MRI examinations are tolerated well. Very similar reactions were obtained from this current study in a clinical setting with a Philips 58 cm bore diameter magnet as reported previously from a Siemens scanner of 59.5 cm bore diameter. The similarities in two completely different settings, with different manufacturers, provide further evidence that patient acceptance of clinical 7 Tesla is not likely to be problematic.

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