# Biologic Effects of 3 Tesla (T) MR Imaging Comparing Traditional 1.5 T and 0.6 T in 1023 Consecutive Outpatients

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**ABSTRACT**

*Background*. The recent use of high and ultra-high magnetic field (MF) systems (3.0 T and above) have raised concerns about biologic effects and safety. Sensory symptoms (magnetophosphenes, dizziness/vertigo, headaches, metallic taste, pain changes, and cognitive effects) have been reported. We monitored 1023 consecutive outpatients undergoing MRI after recent introduction of a 3 T MR unit in our community. *Methods/Design*. Observational study utilizing a pretest and posttest symptom rating scale (0-10) questionnaire presented to subjects undergoing MRI at three different facilities with five MRI machines, specifi cally a 3 T (Philips), three units with 1.5 T (GE, GE, Philips), and one 0.6 T (Fonar) unit to record symptoms before and after study. *Results*. 147 subjects (14%) experienced either *new* ($N$ = 69; 6.7%) or changes ($N$ = 78; 8%) in symptoms. New onset symptoms occurred predominantly with 3 T and female preponderance (75%) [$P$ = .002]. Vertigo/dizziness ($N$ = 28, 5.6%) [$P$ = .001], headache ($N$ = 8), spine pain ($N$ = 11) occurred more frequently on 3 T, whereas magnetophosphenes ($N$ = 8) and metallic mouth symptoms ($N$ = 4) occurred principally in 1.5 T. Seventy-eight subjects (8%) experienced pain symptoms ↑↓ with 75% occurring with 1.5 T. Females were 60%. Forty-three percent of individuals had brain MRIs. Symptoms of vertigo/dizziness, headaches, and magnetophosphenes were more commonly seen in individuals undergoing brain MRIs but other body sites were also represented. *Conclusions*. Although no harmful effects were reported in 1023 cases, an unexpected high rate of 14% of individuals experienced sensory stimulation in both 3 T and 1.5 T units. Females appear to be more magnetically sensitive.

Key words: Cognitive changes, high and ultra-high MRI, magnetic fields, magnetophosphenes, metallic taste, pain, vertigo.

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## Introduction

Conventional MR imaging (MRI) has been performed with 1.5 T and 0.6 T units relying on time-varying magnetic fields and changing gradient sequences to detect underlying structural changes. Experience has demonstrated this to be biologically safe, and the US Food and Drug Administration (FDA) in 2003 extended nonsignificant risk status for MRI up to 8 T.[1-3] Advances in MR technology using ultra-high MF systems >3 T has distinct advantages of improved signal-to-noise ratio (SNR), larger chemical shifts, increased spatial resolution leading to greater accuracy for detecting smaller, previously undetected lesions.[4,5] However, with this doubling of magnetic field (MF) strength (3 T), safety concerns have been raised with demonstration of elevated T waves on ECG, magnetohydrodynamic effects in the blood, etc.[6-9] Additionally, a reassessment of biomedical implant and devices that were previously considered safe at 1.5 T demonstrated of the 109 implants/devices, 4% were considered to have an MF interaction at 3 T and were potentially unsafe.[10] Similar concerns about the biologic effects of the augmented static magnetic fields and radiofrequency induced MF with thermal effects at the cellular and molecular level have been raised. A variety of sensory symptoms have been reported including magnetophosphenes (transient flashes of light), metallic taste in mouth, dizziness/vertigo, headache, cognitive changes, and pain changes. These have been considered temporary, isolated, and rare occurrences.[11,12] Feychting stated that these only occur with MF >2 T.[13] The recent introduction of a 3 T high-field unit in our community as well as increased symptomatology among several patients of author suggested that objective analysis was necessary. We therefore monitored 1023 consecutive outpatients undergoing MRI at five specific facilities.

## Methods/Design

Nine technicians performed MRI scans at the five units and rotated among the three different sites. Before and after each MRI, subjects were presented a questionnaire listing 15 of the most common symptoms reported in the literature as well as additional observed symptoms by the author (Table 2), and they were asked to quantify symptoms if currently present using a validated pain score (VAS 0-10) in which 0 indicated no symptoms and 10 indicated the most severe or worst symptoms. Additionally, in the post MRI questionnaire, they were asked if there were any new symptoms previously unreported and quantify them. Prior questionnaires regarding the 15 most common symptoms used arbitrary rating of barely observable, easily observable, uncomfortable, or overwhelming.[11] We decided to use a VAS 0-10 grading system that has been previously validated for pain, allodynia, and quality of life issues. Many of the symptoms listed in Table 2 have not been validated using this scale. However, we believe the measure reliably quantifies level of discomfort, intensity, etc. Three specific MRI sites participated with a total of five MRI units. A Philips 3.0 T Achieva (superconductive), a GE 1.5 T Twin Speed (superconductive), GE 1.5 T Signa (superconductive), Philips 1.5 T Achieva (superconductive), and a Fonar 0.6 T Upright (electromagnetic) served as sites.

## Statistical Analyses

Chi-square tests of association were used to assess the relationship between presence or absence of symptoms and strength of the magnetic field (Tesla 0.6, 1.5, 3.0). For each chi-square analyses, if two or more table cells had expected values less than 5, the three Tesla categories were changed to two categories: (1) Tesla 0.6 and (2) Tesla 1.5 or 3.0 and the resulting $2 \times 2$ Table was tested with a Fisher exact test. Chi-square results are reported with a $P$-value and exact test results are labeled as "Fisher exact $P$."

All tests were two-sided with a level of significance set at $P < .05$. The Statistical Package for the Social Sciences (version 12.0.2) was used to analyze the data (SPSS, Inc., Chicago, Illinois).

## Results

Mean age of patients tested with the 0.6, 1.5, and 3.0 units was 57.1, 53.4, and 51.6 years, respectively. Percentage of female patients for the 0.6, 1.5, and 3.0 units was 66, 53.8, and 62.4%, respectively.

Of the 1023 patients studied, 69 (6.7%) developed *new* symptoms during the MRI procedure (Table 1). There was a statistically significant relationship between *new* symptoms and strength of the magnetic field ($P = .000$). Percentage of patients developing *new* symptoms with the 0.6, 1.5, and 3.0 units was 0.0, 5.0, and 12.9%, respectively. An analysis of the relationship between sex of patient and *new* symptoms (regardless of strength of magnetic field) revealed that although 56% of the total number of cases were women, 52 of the 69 cases with *new* symptoms (75%) were women [$P = .002$].

When each type of *new* symptom was analyzed separately (Table 2), strength of magnetic field was statistically associated with new onset vertigo ($n = 28$): (0.0% developed vertigo with 0.6 T unit, 1.9% with the 1.5 T unit, and 5.6% with the 3.0 T unit [$P = .001$]). Of the 28 patients who developed vertigo, 13 (46%) had brain MRI studies. Similarly, all four patients who developed metallic taste had brain MRIs.

Of all 1023 patients, 264 (25.6%) had back pain prior to the MRI. Back pain increased for 19 (7.2%) of these patients and all 19 were tested with 1.5 T or 3.0 T units (Fisher exact $P = .05$).

Table 1. Demographic Assessment of Cohort

| | Total Numbers | Males | Females | 3 T | 1.5 T | 0.6 T |
|---|---|---|---|---|---|---|
| Asymptomatic | 257 | 123 | 134 | 100 | 149 | 8 |
| No change of symptoms | 621 | 263 | 358 | 132 | 398 | 91 |
| New symptoms | 58 | 17 | 41 | 34 | 24 | 0 |
| Change of symptoms | 76 | 33 | 43 | 18 | 57 | 1 |
| New and change of symptoms | 11 | 0 | 11 | 3 | 8 | 0 |
| | 1023 | 436 | 587 | 287 | 636 | 100 |

Table 2. Symptom Analysis

| New Symptoms | Total Number | Males | Females | 3.O | Tesla 1.5 | 0.6 |
|---|---|---|---|---|---|---|
| Vertigo | 28 | 7 | 21 | 16 | 12 | 0 |
| Headache | 8 | 2 | 6 | 5 | 3 | 0 |
| Phosphenes | 8 | 1 | 7 | 0 | 8 | 0 |
| Back pain | 5 | 0 | 5 | 3 | 2 | 0 |
| Metallic taste | 4 | 0 | 4 | 1 | 3 | 0 |
| Neck pain | 4 | 1 | 3 | 1 | 3 | 0 |
| Shaky | 2 | 1 | 1 | 1 | 1 | 0 |
| Facial pain | 2 | 0 | 2 | 1 | 1 | 0 |
| Dry mouth | 2 | 1 | 1 | 1 | 1 | 0 |
| Disorientation | 2 | 0 | 2 | 1 | 1 | 0 |
| Extremity tingling | 2 | 0 | 2 | 2 | 0 | 0 |
| Extremity numbness | 1 | 0 | 1 | 1 | 0 | 0 |
| Extremity cramp | 1 | 0 | 1 | 1 | 0 | 0 |
| Extremity pain | 1 | 1 | 0 | 1 | 0 | 0 |
| Extremity warmth | 1 | 1 | 0 | 1 | 0 | 0 |
| Stiff neck | 1 | 1 | 0 | 1 | 0 | 0 |
| Nausea | 1 | 1 | 0 | 1 | 0 | 0 |
| Anxiety | 1 | 0 | 1 | 0 | 1 | 0 |

The overall majority of subjects (86%) did not notice any change. New symptoms of vertigo/dizziness, headache, magnetophosphenes, and metallic taste in mouth are observed more in individuals undergoing brain MRIs, but other study sites are also represented. The role of movement of the eyes, body, extremities was not and could not be quantified.

Six of the 145 (4%) patients with new or changed symptoms had multiple studies. Twenty-three of the 878 (3%) patients with no symptoms or unchanged symptoms had multiple studies.

## Discussion

Most biological tissues are weakly magnetic and specifically diamagnetic. During MRI procedures, three types of emissions arise which could potentially interact with biological tissue. Static magnetic fields (direct current, DC) is always present irrespective whether machine is on or off. During the actual MR procedures, gradient magnetic fields (alternating currents, AC) and radiofrequency (RF) energy directly or by fringe effects are generated inducing electric fields, current, and voltages within the tissues (Faraday's Law, Lenz Law).[14,15] There are three biophysical models that have been proposed to provide a mechanism for the bioeffects of weak AC/DC magnetic field combinations. The ion cyclotron resonance (ICR) and ion parametric resonance (IPR) models[16–18] attempt to explain how ion movement near a binding site or through a membrane channel can be enhanced with specific combinations of AC and DC magnetic fields and do not predict enhanced effects with static fields only. The third model Larmor precession (LPM) predicts effects starting at approximately 0.1G from either DC or AC/DC magnetic fields.[19-20] LPM describes the effects of exogenous magnetic fields on the dynamics of ions in a binding site. A bound ion in a static magnetic field will precess at the Larmor frequency and will accelerate faster to preferred orientations in the binding site with increasing magnetic field strength. Thus, an increased binding rate can occur with a resultant acceleration in the downstream biochemical cascade. Addition of an AC magnetic field to a bound ion already precessing in a binding site in the presence of a static magnetic field will modulate motion. It has been demonstrated that system testers working near the bore of the magnet in MRI machines also experience sensory symptoms compared to a reference department.[12] The static magnetic field produces the above. Additionally, individuals who move their eyes or extremities more rapidly in the RF cage generate a stronger dynamic field inducing complaints compared to individuals who move at a slower pace through this static magnetic field.[11,12] Gradient time-varying magnetic fields also create voltages and induce electric currents within tissue and are known to produce peripheral nerve stimulation and also magnetophosphenes. The latter are spots or light flickering or flashes of light before the eyes, which are believed to be generated by rotation, alignment changes, or torque on the retinal rods that are diamagnetic. These currents are quite significant within the ultrahigh MRI and thus the FDA limits the switching rates necessary to generate these gradient fields to a factor of three below the mean threshold of peripheral nerve stimulation.[4,10] Very high static magnetic fields are able to induce a voltage within the endolymph within the labyrinth producing magnetohydrodynamic forces inducing symptoms of dizziness, imbalance, and vertigo. Similarly, the sensation of a metallic taste in the mouth is considered secondary to intraoral flux density reacting with the dental amalgam (electrolysis). The static magnetic fields also contain an alternating current time-varying component, producing secondary currents in the oral tissue and restorative materials. If two types of metals are used in two different and adjacent dental fillings, ie, silver/mercury, a battery effect can be created. The role of mercury and iron has also been postulated to play some role.

The increase in spine complaints with pain may be a reflection of ion/ligand stimulation or perhaps reflect an uncomfortable sustained position for the performance of the test. It has been stated that the inevitable movement of the body while in the magnetic field tends to induce electric currents within the tissues.[11-13,21,22] Anxiety and stress about the procedure are *not* considered pertinent to causation. The literature indicates that the number of complaints increased significantly with duration of exposure to static magnetic field(s).[11,12] We did not measure subject time within the machine, yet the standard sequences were performed in all cases when able.

In terms of safety, there were no lingering effects and the complaints were to be considered transitory and not a harbinger of disease.[11,23] While many of the described symptoms have been previously mentioned in the literature, the unanticipated and surprisingly high rate of 14% of subjects experiencing sensory symptoms (new or altered) with both 3 T or 1.5 T is bothersome and suggests that a threshold exists for magnetic susceptibility as well as sexual vulnerability. From a scientific perspective, it would have been ideal to expose symptomatic individuals to the other MRI systems or sham exposure to test for specific thresholds and placebo effects, but this was a community observational study only. Future protocols could explore this issue.

Irrespective of what type of scan is being performed, magnetic field exposure can induce biophysical changes within the tissues. Physicians and technicians should provide additional informed consent regarding MRI scanning especially in women.

## Summary Statement

The unanticipated and surprisingly high rate of 14% of subjects experiencing sensory symptoms (new or altered) with both 3 T or 1.5 T is bothersome and suggests that a threshold exists for magnetic susceptibility as well as sexual vulnerability.

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