Original Research

Effect of Static Magnetic Field Exposure of Up to 8 Tesla on Sequential Human Vital Sign Measurements

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Purpose: To determine if increasing static magnetic field strength exposures up to 8 Tesla (T) affect vital signs or electrocardiograms (ECGs) in normal human volunteers.

Materials and Methods: We studied 25 normal subjects, consisting of 19 men and six women, ages 24–53 years. The vital signs and ECGs of the subjects were measured 14 times inside and outside the magnetic field. This included the heart rate, respiratory rate, systolic and diastolic blood pressures, finger pulse oxygenation levels, core body temperature via the external auditory canal temperature, and fiber optic core body sublingual temperatures. Inside the magnetic field the vital signs were measured sequentially at field strengths of 8, 6, 4.5, 3, and 1.5 T.

Results: The only statistically significant effect of magnetic field strength was observed with systolic blood pressure. An average increase of 3.6 mm Hg in systolic blood pressure was seen with 8 T exposure. ECG rhythm strip analysis demonstrated no significant changes post-exposure.

Conclusions: Normal subjects exposed to varying magnetic field strengths of up to 8 T demonstrated no clinically significant changes in vital signs. Transient ECG artifacts were noted to increase with the field strength.

Key Words: MRI safety; high field MRI; biologic effects; static magnetic field; vital signs
J. Magn. Reson. Imaging 2003;18:346–352.

THE AVAILABILITY OF high-static magnetic fields to provide higher resolution and greater spectral separation in magnetic resonance imaging (MRI) and spectroscopy (MRS) has increased. To assure patient safety, a full understanding of the effects of magnetic fields on human physiology is required (1–4). Experiments presented in this article enhance the understanding of the potential human health implications of MRI at very high static magnetic field strengths up to 8 Tesla (T) for human subjects (5–18). Considering the recent and the anticipated future proliferation of human high-field MR systems and the previous and current experience establishing the feasibility of using greater than 4 T MR systems for examination of human subjects, a detailed scientific study to evaluate the effects on vital signs and electrocardiographic (ECG) recordings and the safety of human imaging at very high magnetic field strength is necessary and important. Over 500 human subjects have been reported to the FDA to have been evaluated at field strengths of 7 and 8 T without the occurrence of a significant adverse event. Information on the systematic evaluation of the effect of these high magnetic fields on vital signs is not available.

Of our first 130 human subjects (not included in these 25 subjects) exposed to 8 T, one vomited and a few demonstrated changes in their vital signs before and after their high-field exposure. We have never recorded a symptomatic vital sign change. Continuous detailed vital sign measurements were not available on the first 130 subjects. This work focuses on the acquisition of a randomized detailed series of physiologic vital sign measurements at different field strengths. These measurements were made to evaluate and define the normal range of vital sign changes encountered in the high-field setting and to determine if there was a measurable effect resulting from exposure to various magnetic field strengths that might present a potential health risk to human subjects.

MATERIALS AND METHODS

The system used included a Bruker Avance (Billerica, MA) console interfaced to a Magnex-General Electric (Abingdon, UK) 8 T/80 cm bore MRI scanner. The Institutional Review Board approved the study protocol. All subjects who participated in this study signed informed consent forms. Subjects from ages 18–65 years

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Received December 16, 2002; Accepted May 15, 2003.
DOI 10.1002/jmri.10367
Published online in Wiley InterScience (www.interscience.wiley.com).

Table 1
Experimental Design Clarified

Randomized to magnet first	Presitting 0T	Presupine 0T	8T	6T	4.5T	3T	1.5T	0T	0T	0T	0T	0T	Postsupine 0T	Postsitting 0T
Randomized to magnet second	0T	0T	0T	0T	0T	0T	0T	8T	6T	4.5T	3T	1.5T	0T	0T
Supine		*	*	*	*	*	*	*	*	*	*	*	*	
Sitting	**													**
Five minute intervals	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N
Head in coil	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N
Respiratory rate	Y	Y	N	N	N	N	N	N	N	N	N	N	Y	Y
EAC temperature	Y	Y	N	N	N	N	N	N	N	N	N	N	Y	Y
Sublingual temperature	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N
SBP	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
DBP	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
HR	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Pulse oxygenation	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
ECG	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

A series of vital sign measurements were made 14 different times. The preexposure measurements were acquired in both the sitting and supine positions out of the head coil. External auditory canal temperatures and respiratory rates were also measured. Each subject was randomized to a series of 10 measurements spaced at five minute intervals after the head was placed in the head coil. Fiber optic sublingual temperature measurements were acquired for this group. The order of the first five measurements as to whether the field exposure was first or second was randomized. The magnetic field exposures progressively decreased from 8 to 1.5 T. After these 10 measurements the head was removed from the coil and similar measurements to the preexposure interval were obtained.
* = supine, ** = sitting, Y = yes, N = no, SBP = systolic blood pressure, DBP = diastolic blood pressure, ECG = electrocardiogram.

were recruited with no preferences as to sex. Twenty-five subjects, 19 males and six females, between the ages of 24 and 53 years (mean = 35 years) were studied. Subjects were excluded based on routine safety standards (9) and the following criteria: subjects who suspected they may be or might have become pregnant (if reasonable doubt existed, self-testing with a study-provided over-the-counter urine pregnancy kit was required); subjects who could not adhere to the experimental protocols for any reason; subjects with an inability to communicate with the researcher; subjects with cardiac or known circulatory impairment and/or an inability to perspire or with conditions known to compromise thermoregulatory function (sweating or perspiration disorders); subjects who were on medications that may have altered their vital signs and/or their ability to control their temperature, e.g., beta blockers; prisoners; subjects who had limited mental ability to give informed consent or who were mentally retarded, had altered mental status, mental disability, confusion, or psychiatric disorders; subjects whose vital signs were not within the range of normal; and subjects with diabetes mellitus, heart disease (angina, arrhythmia, congestive heart failure), chronic obstructive pulmonary disease, autonomic disorders, or hearing disorders.

Subjects were asked to remove all metallic objects or clothing having any metallic components. The MRI staff carefully inspected the subject for potential metallic objects. Prior to the procedure subjects were asked to fill out a standard questionnaire.

Respiratory rate was visually counted only when the subject was outside of the magnetic field. The external auditory canal (EAC) core body temperature was also measured only when the subject was outside of the magnet, using a digital electronic temperature measurement device. Other vital signs were measured automatically using an Omni-Trak IN VIVO Research (Orlando, FL) remote monitoring system. The remote monitoring system measured the pulse rate and oxygen levels based on a fiber optic finger pulse oxygenation meter, electrocardiogram (ECG), systolic and diastolic blood pressures. The 790 Luxtron (Santa Clara, CA) unit was used to measure core sublingual temperatures with an accuracy of 0.1°C. The body temperatures were normalized as closely as possible between the EAC temperature and the sublingual temperature by measuring the two temperatures on each subject and comparing the values. The measured EAC temperatures were not as consistent as the measurements obtained using the Luxtron system.

Table 1 lists the experimental design of 14 series of vital sign and ECG measurements. The pre-exposure measurements were made initially sitting, then supine. This change in position allowed for a measure of potential changes of vital signs that are known to be benign. The head was not placed in the head coil to avoid any potential effects of claustrophobia. We could also measure the EAC temperature and count the respirations visually. The post-exposure measures were made in an identical fashion.

Prior to any magnetic field exposure, the heart rate, ECG, systolic and diastolic blood pressure, and finger pulse oxygenation level were also measured. The Luxtron probe was then placed sublingually and the subject's head was enclosed in a 16-strut transverse electromagnetic (TEM) head coil. No radio frequency (RF) energy was utilized in this study. The purpose of using the coil was to simulate as closely as possible the hardware used in an actual MRI experience. The order (whether inside or outside the magnetic field) of the collection of the next 10 supine measurements was randomized (Table 1), five were obtained inside the magnetic field (at five locations corresponding to different field strengths) and five were obtained outside of the field at five minute intervals. For the measurements which were done first "inside" the field, the subject was slowly advanced on a mobile table into the magnet until

Table 2
Field Strength vs. Anatomic Structure

Head	Chest	Feet
8 T	8 T	2.3 T
6 T	3.7 T	0.2 T
4.5 T	2.5 T	0.13 T
3 T	1.66 T	0.09 T
1.5 T	0.8 T	0.04 T

The approximate magnetic field strength for the head, chest, and feet for each of the five locations where the vital sign measurements were made are listed. The subject is assumed to be 175 cm tall and the chest is 30 cm from the top of the head.

the head was at a location corresponding to an 8 T field strength. The subject was advanced to approximately the 3 T position by rolling the table to the magnet bore. The cantilevered segment of the table was then manually advanced more slowly, in short steps of one to two feet over a few seconds, followed by the subject remaining stationary for 15–30 seconds. The total rate of magnet entry was quite slow and occurred over approximately a three to four minute interval. The slowest advancement occurred at the bore of the magnet. The temperatures in the magnet were 16.4°C at the head, 20.9°C at the chest and 21.9°C at the feet. The temperature was 22.4°C in the control room. Vital signs were recorded every five minutes at the position of the subject's head corresponding sequentially to 8, 6, 4.5, 3, and 1.5 T field strengths. These magnetic field strength "locations" corresponded to the static magnetic field strength present at specific distances from the center of the magnet, with the field strength decreasing as the movable table was moved further from the center of the magnet. Table 2 displays the magnetic field strength for the head, chest, and feet for each magnetic field strength position. The subject is assumed to be 175 cm tall and the chest is assumed to be 30 cm from the top of the head.

After these five sets of measurements were made, the subject was removed completely from the magnetic field ("outside") and a second series of five similar measurement sets were made at five-minute intervals (Table 1). Half of the subjects were randomized to having a series of identical measures, the first five outside of the magnetic field, then the next five at decreasing field strengths (8–1.5 T) (Table 1). After these 10 measurements, the head coil was removed and the vital signs were measured as pre-exposure in the supine position outside of the magnetic field. A final set of measurements was collected with the subject sitting in an upright position.

The subject was asked to fill out a form immediately after the procedure to record any comments related to their experience during the examination. They were asked three questions: 1) how did you feel during the exam; 2) how did you experience any unusual sensations during the study; and 3) any other comments? A three-month follow-up was also obtained asking the subjects only if they had any comments.

A cardiologist reviewed the ECGs from every subject.

A repeated measures analysis of variance was used to determine the significance of the effects of position (sitting vs. supine), measurement interval (pre-, during, and post-MRI), and field strength on heart rate, core temperature, blood level oxygenation, and systolic and diastolic blood pressure. For field data, we fit individual linear regression lines to subjects and took the mean slope of all the lines to estimate the magnitude of individual effects. A 0.05 level of significance was used.

RESULTS

No subject commented on any significant symptom associated with the immediate high magnetic field exposure. Overall 23 of the 25 subjects stated that they were "fine," "relaxed," "nothing," "normal." or "good." The number of times subjects commented on transient symptoms was—dizziness, nine; a metallic taste while entering the magnet, two; and nystagmus, one. Four subjects commented on discomfort associated with the vital sign measurements, most commonly the finger pulse oxygen saturation device. Three subjects commented on the discomfort of the head coil. Twenty-four of the subjects stated that they had no adverse events three months later. One subject declined to comment. At the three-month follow-up there were no adverse comments.

Table 3 and Figures 1–5 show the results for the effects of position, measurement interval (pre-, post-, and during exposure), and field strength on each vital sign measurement. The effect estimates show the magnitude of the effect sizes, with positive signs reflecting an increasing effect and negative signs reflecting a decreasing effect. For every vital sign measurement, position was highly significant with all P values < 0.0001. For example, with heart rate, the supine position resulted in a decrease by 6.48 beats per minute when compared to the sitting measurement (Fig. 3). Diastolic blood pressure showed a decrease of 6.97 mm Hg when the subject moved from a sitting to a supine position (Fig. 2). Core body temperatures showed an increase of 0.27°C when the subject was lying down (Fig. 5).

Differences in vital sign measurements based on field strength exposure were not statistically significant for heart rate, oxygen saturation, diastolic blood pressure, or core temperatures, with P values of 0.17, 0.32, and 0.09, respectively. However, a statistically significant ($P = 0.027$) increase in the systolic blood pressure was seen with increasing field strength (Fig. 1). Given the effect size, when the magnetic field was increased from 0 T to 8 T, an increase of 0.45×8, a maximum of 3.6 mm Hg was seen. For comparison, this increase is approximately one-half of the increase seen when the subject changes from a supine position to a sitting position.

The intercepts for the five vital signs presented in Table 3 reflect the results of the regression model in fitting the vital sign data. The intercept reflects the baseline model prediction when all factors are at their zero or reference level. For all vital signs, this baseline intercept occurs when: 1) sitting (this includes data from the post-exposure sitting position); 2) the pre-exposure measurement interval (this includes both supine and sitting); and 3) an exposure of 0 Tesla (this includes the 0 Tesla when inside the magnet as well as the 0 Tesla pre- and post-exposure measurement inter-

Table 3
Statistical Results of Vital Sign vs. Magnetic Field Strength

Vital sign	Factor		Effect estimate	Standard error	*P* value
Heart rate (per minute)		Baseline/sitting	72.68	1.70	
	Position	supine	−6.48	0.67	<.0001
	Measurement interval	Pre-, during, post-	−1.90	0.43	<.0001
	Field strength (/Tesla)		0.20	0.14	0.17
Oxygenation		Baseline/sitting	98.10	0.40	
(% saturation)	Position	supine	−1.27	0.23	<.0001
	Measurement interval	Pre-, during, post-	0.17	0.15	0.25
	Field strength (/Tesla)		0.04	0.03	0.17
Systolic blood		Baseline/sitting	127.94	2.82	
pressure	Position	supine	−6.47	1.28	<.0001
(mm Hg)	Measurement interval	Pre-, during, post-	−1.74	0.81	0.03
	Field strength (/Tesla)		0.45	0.19	0.027
Diastolic blood		Baseline/sitting	81.18	1.86	
pressure	Position	supine	−6.97	0.73	<.0001
(mm Hg)	Measurement interval	Pre-, during, post-	−1.24	0.46	0.008
	Field strength (/Tesla)		0.10	0.10	0.32
Core Temperature		Baseline/sitting	36.15	0.09	
(C)	Position	supine	0.27	0.05	<.0001
	Measurement interval	Pre-, during, post-	−0.07	0.03	0.026
	Field strength (/Tesla)		0.02	0.01	0.09

The effects of position (supine or sitting), measurement interval (pre-; post-, during exposure), and field strength on vital sign measurements as compared to baseline sitting rates are listed. The absolute magnitude (effect estimate) and statistical significance (*P* value) of each factor is listed. For example, going from a sitting to supine position results in a significant 6.5 beats per minute reduction in heart rate from 72.7 to 66.2 bpm, but an insignificant increase of 1.6 bpm (0.2×8) going from 0 to 8T.

vals. By defining the model in this manner, we can better estimate the effects of the three factors. As a result, the baseline intercept does not actually reflect the mean of the pre-exposure sitting values presented in Figures 1–5.

A typical ECG rhythm strip series is shown in Figure 6. While the heart rate was approximately the same, artifacts were seen, presumably due to magnetic interference. Similar changes were identified in all individuals. ECG rhythm strips pre- and post-exposure were unchanged.

DISCUSSION

Due to many inherent physical and imaging advantages, there has been a progressive increase in magnetic field strength, increasing gradient strength, and increasing frequency of the RF energy used for human

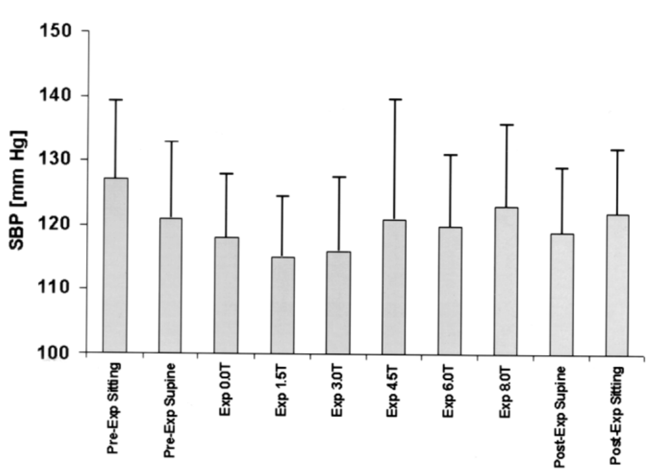

Figure 1. Systolic blood pressure (SBP), position, time, and field strength. This graph shows the average and the standard deviation for the SBP related to timing (pre- or post-exposure), position (sitting or supine), and magnetic field strength. There was a clinically insignificant trend of increasing SBPs with increasing magnetic field strength.

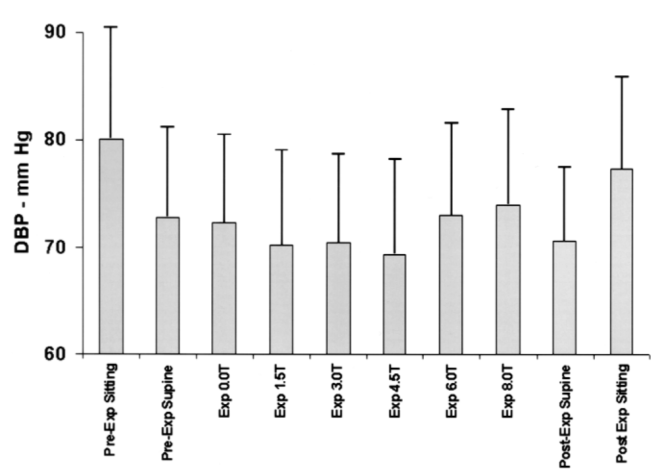

Figure 2. Diastolic blood pressure (DBP), position, time, and field strength. This graph shows the average and the standard deviation for the DBP related to timing (pre- or post-exposure), position (sitting or supine), and magnetic field strength. There was no relationship between DPB and increasing magnetic field strength.

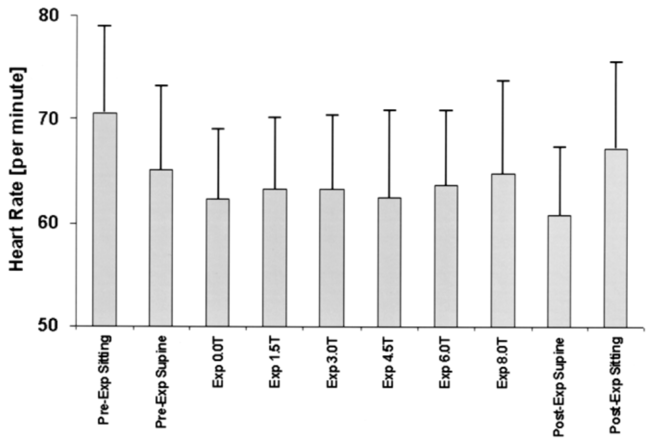

Figure 3. Heart rate, position, time, and field strength. This graph shows the average and the standard deviation for the heart rate related to timing (pre- or post-exposure), position (sitting or supine), and magnetic field strength. There was no relationship between heart rate and increasing magnetic field strength.

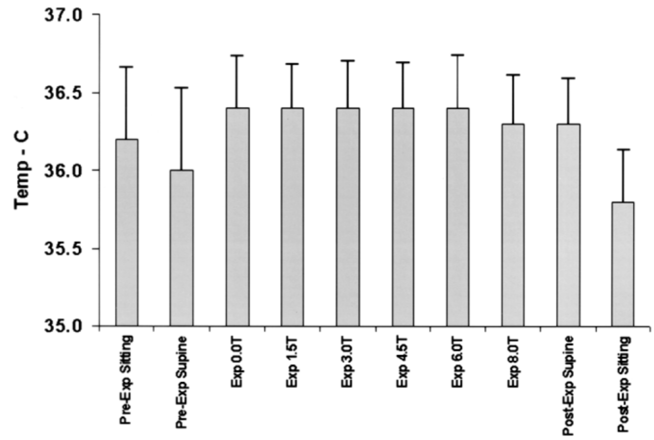

Figure 5. Core body temperature, position, time, and field strength. This chart plots the average and standard deviation of the core body temperature vs. location (inside or outside of the magnetic field), position (supine or sitting) and time (pre- or post-exposure). The most accurate measurements were made with the sublingual Luxtron unit and they demonstrated no significant changes with magnetic field strength.

imaging (1–4). At each field strength increase it has been necessary to resolve potential new safety questions (19). The work completed in this study extends the scientifically evaluated human safety exposure up to 8 T, opening up the possibility of utilizing high field human MRI in a clinical setting to better define many pathologic states.

The United States Food and Drug Administration (FDA) has approved exposure to 4 T in commercially available clinical systems. Animal studies performed in long-term static magnetic field strengths of up to 9.4 T have shown no adverse effects on mammals (20). Previous studies have shown that there are no major vital sign changes related to static magnetic fields up to 1.5 T (10–12,15).

One commonly reported transient benign high-field effect is dizziness or vertigo. The magnetic field may induce currents in the labyrinthine system or in the motion of otoliths. This is most common on first entering the magnet bore and is exacerbated by rapid head motion through the highest magnetic field gradients. Nystagmus may accompany this sensation, providing an objective physical finding associated with the magnetic field effect. Nystagmus results from vestibular response and is closely tied to brain stem nuclei that control autonomic function, which could induce secondary vital sign changes. We have significantly reduced the incidence and intensity of these symptoms by slowing the subject entry and exit time into and out of the field, taking a few minutes to move the subject from 3–6 T. Frequent intervals of no motion were utilized. Though the most common subject comment was related to dizziness, none of the subjects found it to be significantly disturbing.

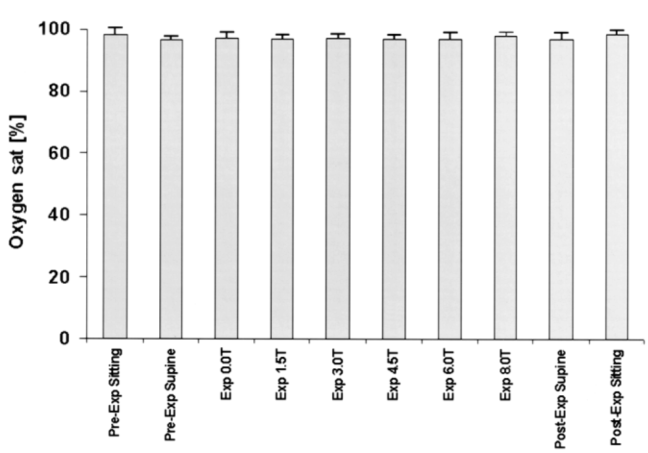

Figure 4. Blood oxygen saturation, position, time, and field strength, This graph shows the average and the standard deviation for the blood oxygen saturation levels related to timing (pre- or post-exposure), position (sitting or supine), and magnetic field strength. There was no relationship between the oxygenation level and any of the factors.

The appearance of magnetophosphenes (bright visual images similar to those seen when rubbing one's eyes) have been reported by subjects being imaged in high field, but this was not reported by any of our subjects. Reports of a transient metallic taste in the mouth are probably due to electrolysis of metallic chemicals in the subjects' teeth fillings as they are moved through the magnetic field.

In our studies of the first 130 subjects, that did not include these 25 subjects, we measured pre- and post-magnetic field exposure vital signs on many subjects, but not all. While one of the 130 initial subjects vomited, no significant adverse effects were reported. These subjects included some patients with history of stroke, demyelination, and brain tumors.

Major vital sign changes in subjects having existing or underlying pathology may be particularly clinically significant. For example, patients with cerebrovascular disease may be prone to infarction or hemorrhage resulting from increases or decreases in blood pressure. Increased blood pressure can also be a risk in cases of vascular lesions such as arteriovenous malformations

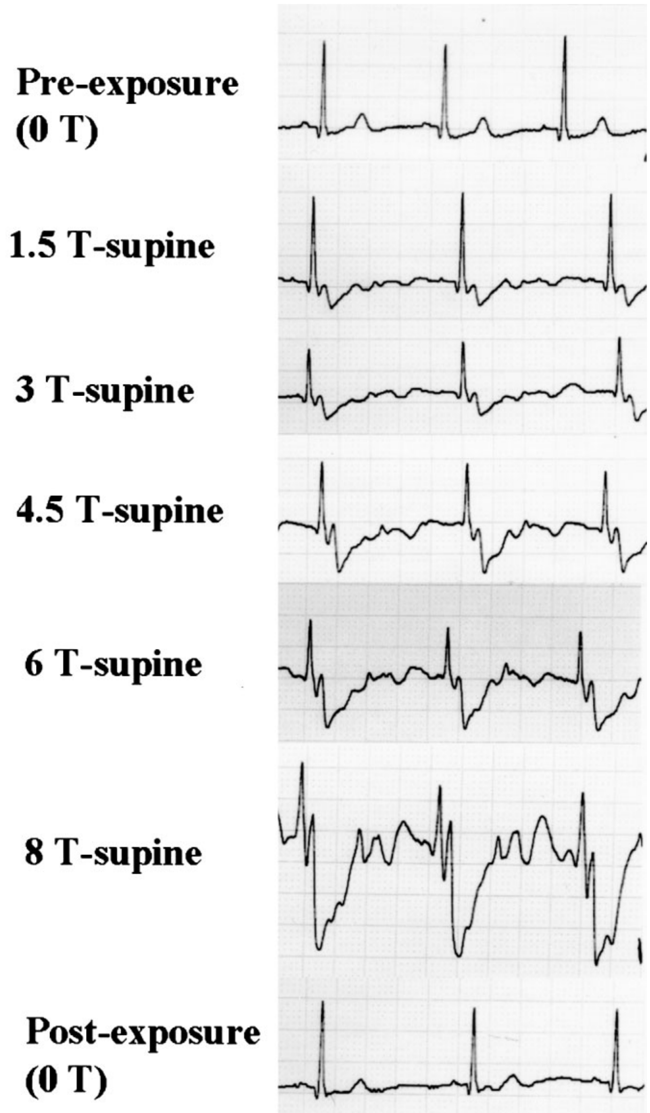

Figure 6. Sequential electrocardiograms pre-exposure, post-exposure, and during exposure to increasing magnetic field strength. This figure demonstrates the ECG recording of a single individual pre-exposure (0 T), during exposure (8, 6, 4.5, 3, 1.5 T) and post-exposure (0 T). Note the distortions of the ECG with increasing magnetic field strength.

and aneurysms. When a change in vital signs was encountered, follow-up measures were made to confirm the finding and the subject was asked if they were symptomatic. The blood pressure measurements are mechanical and are probably particularly sensitive to variations. An additional factor in blood pressure monitoring variation might be that the subjects' arm position changed from inside to outside of the magnet due to changes in the arm table support. Because of this, some of the measured changes might be artifactual, occurring if the blood pressure cuff comes into contact with the sidewall of the magnet.

This study shows that measured vital sign changes (Table 3, Figs. 1–5) related to a sitting or supine position are larger than those associated with exposure to a static magnetic field. Based on this finding it is suggested that the static magnetic field is safe in terms of changes that are within the normal physiologic range. Orthostatic changes in the vital signs are well-known normal variations that occur with position, as was recorded in this study. The only statistically significant vital sign measurement related to magnetic field strength was the systolic blood pressure, but the actual changes were so small that they are clinically insignificant (a 3.6 mm Hg increase over the 8 T range).

We measured no impact of the magnetic field on core body temperature.

As previously reported, this study extends the static field strength to 8 T from 1.5 T. There was no RF exposure to induce any temperature changes. If there had been any changes they would have been attributable to the static field.

There was no clear measurable effect of the magnetic field strength on vital signs. The actual greatest gradient change is at the bore of the magnet. We instructed the subjects not to move their head during entry to the magnet therefore suppressing potential exacerbation of symptoms. We did not evaluate the gradient effect if the subjects entered the magnetic field feet first where the head would be closer to the high gradient. The interaction of the blood flow with the magnetic field, or magnetohydrodynamics (MHD), has been advanced as being capable of increasing the blood pressure. Our early results demonstrated that MHD had caused an overestimation of the increase in blood pressure needed to sustain the flow in the aorta for high magnetic fields (19).

There were ECG artifacts that increased with the magnetic field strength (Fig. 6). This is the well-known MHD effect (21). The MHD effect produces a transverse electromotive force as a result of flow of a conducting medium within a strong magnetic field. This electromagnetic force, in turn establishes a finite voltage around the area where the blood flows. This electric voltage is indistinguishable from the electrical events that generated the ECG signal, causing the artifactual MHD signal to be overlaid on the ECG signal. ECGs returned to baseline immediately after leaving the magnetic field.

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