Evaluation of Continous Vital Sign Measurements at Multiple Static Magnetic Field Stengths to 8 Tesla

D. W. Chakeres[1], A. Kangarlu[1], H. Boudoulas[1], D. C. Young[1]

[1]The Ohio State University College of Medicine and School of Public Health, Columbus, Ohio, United States

Synopsis

This study examines the effects of static magnetic field strengths up to 8 Tesla on the vital sign physiology of 25 human subjects. Pulse rate, respiratory rate, electrocardiogram (ECG), systolic and diastolic blood pressures, finger pulse oxygenation levels, core body temperature (via the external auditory canal), and multiple fiber optic temperatures were repeatedly measured. The quantitative measures were then statistically analyzed. The largest statistically significant changes observed were related to the transition from supine to upright outside of the magnetic field. One statistically significant correlation was observed between the systolic blood pressures and field strength, but it had no clinical significance

Methods

All studies were done under Investigational Review Board supervision. All human subjects signed informed consent. Prior to the procedure subjects were asked to fill out a standard questionnaire. Subjects were potentially excluded based on a number of criteria such as pregnancy and metallic implants. We studied 25 normal subjects, 19 men, 6 women, ages 24-53 (mean 35) years. A series of vital sign measurements were made in and out of the magnetic field 14 different times including both the sitting and supine position. Respiratory rate was visually counted out of the magnet only. The external auditory canal (EAC) core body temperature was measured manually outside of the magnet only using an electronic temperature device. The other vital signs were measured automatically using either an Omni-Trak IN VIVO Research (Orlando, Florida) remote monitoring system or a Luxtron 790 (Santa Clara, California) four-probe fluoroptic temperature measuring system. The remote monitoring system measured the pulse rate based on a finger pulse oxygenation meter, electrocardiogram (ECG), systolic and diastolic blood pressures, and finger pulse oxygenation level. A four-probe Luxtron unit was used to measure three separate temperatures: core body- sublingual, skin forehead, and skin cheek. The body temperatures were normalized as closely as possible between the EAC temperature and the sublingual temperature by measuring the two temperatures on one subject.

The subject was advanced into a 16-strut transverse electromagnetic (TEM) head coil, but there was no radio frequency exposure. The order of the measurements was randomized, determining whether they were taken in or out of the magnetic field first. A series of 10 measurement series, 5 in the magnetic field and 5 out were collected. The subject was slowly advanced until the head was at 8 T field strength. Every 5 minutes a series of measurements were made and recorded at 8, 6, 4.5, 3, and 1.5 T field strengths at the head. These magnetic field strength "locations" correspond to the static magnetic field strengths present at specific distances from the center of the magnet, with the field strength decreasing as the gantry table is moved further from the center of the magnet. The subject was removed completely from the magnet and a series of 5 similar measurements were made every 5 minutes. The temperature was 16.4 ° C in the bore of the magnet. Based on a randomization table, five measurements were made out of the magnet then the subject was advanced into the magnet for five more measurements. After exposure, the head coil was removed and the vital signs were taken in the supine position using the same technique as before exposure. Finally, a series of measurements were made with the subject in an upright position. The subject was asked to fill out an experience form to note any comments. A cardiologist reviewed the ECG traces. The quantitative measures were analyzed statistically for any trends. We used a repeated measure analysis of variance to evaluate the effects. For field data, we fit individual linear regression lines to subjects and took the mean slope of all the lines. We computed the estimate of the effect of each of the independent factors, its standard error, and the P value for that factor. Significant effects had $P = 0.05$ or less. The comments made by the subjects were reviewed.

Results

There were spontaneous variations in the vital sign measurements out of the magnet field, particularly in the pulse and blood pressure. The pulse oxygenation levels and the core body temperature as measured by the sublingual probe were very stable. The skin temperatures increased up to more than one degree C without any RF exposure, both in and outside the magnetic field.

The position (upright or supine), period (pre, during, or post exposure), and magnetic field strength were evaluated as independent factors with the vital sign data as dependent variables. The results for each dependent variable were statically analyzed. For every vital sign, position was highly significant with all P's < 0.0001. The estimates show the magnitude of the effect, with positive signs reflecting an increasing effect, while negative signs reflect a decreasing effect. For example, with heart rate, the supine position resulted in a decrease by 6.48 beats per minute. Diastolic blood pressure showed a decrease of 7 mm Hg going from a sitting to a supine position. Differences in vital signs based on field strength were not statistically significant for heart rate, oxygen level, diastolic blood pressure, or core temperatures, with P values of 0.17, 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. Given the effect size, in increasing the magnetic field from 0 T to 8T, we see an increase of [0.45 x 8] or 3.6 mm Hg. This increase is approximately one-half of the increase seen when the subject sits up after being in a supine position. The ECG traces demonstrated transient increasing changes with increasing field. All ECGs were normal before and after exposure. Overall twenty-three of the twenty-five subjects stated that they were "fine", "relaxed", "nothing", "normal", or "good". A few subjects commented on transient symptoms including: dizziness, a metallic taste while entering the magnet, and nystagmus.

Discussion

There has been a progressive increase in magnetic field strengths, increasing gradient strengths, and increasing frequency of the RF energy used for human imaging because of many inherent physical advantages (1-3). At each incremental increased step there have been safety questions that have needed to be resolved. The Food and Drug Administration (FDA) guidelines have expanded the non-significant risk designation to field strengths of up to 4 T. Animal mammal studies with long-term static magnetic field strengths up to 9.4 T have not shown adverse effects (4). One commonly reported benign transient high field effect is dizziness or vertigo. We have significantly reduced the incidence and intensity of these symptoms by slowing the entry time into the field, allowing a few minutes to make the transition from 3- 6 T. Transient metallic taste in the mouth is probably due to electrolysis of metallic chemicals from fillings as the subject moves through the magnetic field.

Even minor vital sign changes of subjects with pathology may be clinically significant. We did not measure any clinically symptomatic vital sign changes related to the magnetic field. The only statistically significant correlation found was with systolic blood pressures, but the statistical finding was not clinically significant. It was also noted that there were spontaneous temperature changes of the facial skin, possibly resulting from blushing. There was no RF exposure to account for any focal induced heating. Since there were spontaneous changes in the skin temperatures, evaluation of temperature changes due to local RF heating may be difficult to unequivocally define. We did not see any impact of the magnetic field on the core body temperature.

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