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Physiologic Changes During High Field Strength MR Imaging

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High field strength MR imaging systems may require several kilowatts of RF power to obtain images. A fraction of this power is absorbed by the patient, and changes in body temperature have been measured in experimental animals. The purpose of this study was to quantify changes in body surface temperature and other physiologic parameters in humans during MR scanning at 1.5 T. Blood pressure, heart rate, respiration, and axillary temperature measurements were obtained on 27 normal volunteers. Measurements were made at RF power levels of 0, 0.2, and 0.8 W/kg, with the power sequence randomized. In 14 volunteers receiving lumbar scans, statistically significant increases in temperature were observed at RF power levels of 0.2 ($+0.2 \pm 0.1^\circ \text{C}$) and 0.8 ($+0.5 \pm 0.1^\circ \text{C}$) W/kg. No significant changes related to RF power were observed in blood pressure or respiratory rate. At the 0.8 W/kg level there was a slight increase in heart rate (3 ± 1.3 beats per minute). In the 13 patients receiving head scans, physiologic changes were substantially smaller. The temperature increases and other physiologic changes observed during MR scanning with the 1.5 T imager at RF powers of 0.2 and 0.8 W/kg were small and of no clinical concern. Additional studies should be performed in patients with cardiac failure, vascular occlusion, and metallic implants or prostheses.

Before approving MR systems for commercial use, the U.S. Food and Drug Administration (FDA) issued guidelines to MR manufacturers, investigators, and institutional review boards requiring manufacturers and investigators to provide an analysis of health effects to the institutional review boards when RF power deposition exceeds the FDA's recommended specific absorption rate (SAR) of 0.4 W/kg averaged over the whole body or 2.0 W/kg in any gram of tissue. This allows the institutional review boards to rule whether a given system represents a potential risk to patients. The FDA guidelines were based on recommendations of the American National Standards Institute (ANSI) for individuals who are chronically exposed to RF radiation [1]. The ANSI committee arrived at the 0.4 W/kg limit for whole-body exposure by dividing the minimum value expected to cause effects by a safety factor of 10. The minimum value was based on animal data, which showed that feeding behavior was altered after 60 min exposure to RF of 2450 MHz [2]. Behavior changes were observed at power absorptions of approximately 4.5 W/kg averaged over the entire body [2].

The increasing use of high field strength MR systems (1.5–2.0 T) has led investigators to examine the effect of RF power that exceeds FDA guidelines [3, 4]. RF deposition problems are important considerations with high field strength systems because, other factors being equal, the amplitude of RF excitation pulses increases as the square of the strength of the field [5]. The acquisition of multiple echoes and thin slices for clinical evaluation requires rapid pulse rates if the examination is to be tolerated by the patient. These rates may increase the power deposition above the SAR of 0.4 W/kg averaged over the whole body. The FDA's major concern regarding increased power deposition is its effect on body temperature. In our institution we use a high field strength MR system (1.5 T), which has been granted premarket approval by the FDA for operation at 0.4 W/kg whole-

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body SAR and 8.0 W/kg peak SAR. We anticipated we would exceed FDA guidelines in certain clinical examinations using rapid pulsing rates. In order to examine the effects of higher RF power levels we therefore measured temperature and several other physiologic parameters that would indirectly indicate the effect of increased heat absorption at SARs of 0.2 and 0.8 W/kg.

Materials and Methods

Twenty-seven volunteers were randomly divided into two groups: 13 for head imaging and 14 for lumbar imaging. A consent form, approved by the Human Subjects Committee, was obtained from each volunteer and then three scans were performed on each subject: a control scan without RF power but with gradient switching, and scans at two power levels. In the lumbar group one scan exceeded the FDA guidelines of 0.4 W/kg while the other did not. The scans were performed in random order and were all 17 min long. A period of at least 9 min between exposures was used to monitor the physiologic parameters and provide a preexposure baseline.

In this study the SAR was calculated for each patient exposure by an algorithm in the MR computer system. The algorithm was based on data the manufacturers obtained from volunteers scanned in the same areas as in this study. The SAR values in those studies were determined by measuring the loaded and unloaded RF coil impedance and calculating coupling efficiency. From this information and, taking into account transmission-line losses, it was possible to determine the percent of the total measured RF energy that was absorbed by the patient (Schaefer J, unpublished data).

The volunteers who received lumbar scans received nominal SARs of 0.0, 0.2, and 0.8 W/kg. The average (\pm SD) SAR values calculated for the exposures were 0.0, 0.20 (± 0.06), and 0.75 (± 0.14) W/kg. The 0.2 W/kg exposure imaged four slices while the 0.8 W/kg exposure imaged 17 slices. The scans were performed on a 1.5-T

GE MR Signa scanner with a TE of 40 msec and 80 msec, respectively, a TR of 2000 msec, and a slice thickness of 5 mm. The scanner in our institution uses a linear coil.

The head-scan volunteers received nominal average SARs of 0.0, 0.02, and 0.06 W/kg. The average (\pm SD) SAR values calculated for the exposures were 0.0, 0.022 (± 0.004), and 0.058 (± 0.001) W/kg, respectively. The 0.02 W/kg exposure imaged seven slices and the 0.06 W/kg exposure imaged 17 slices. The scans were obtained with a TE of 40 msec and 80 msec, respectively, a TR of 2000 msec, and a slice thickness of 5 mm.

The physiologic parameters measured included temperature, blood pressure, heart rate, and respiratory rate. The temperature was measured in the axilla using a thermistor probe and temperature indicator (YSI). Baseline temperature readings were taken before the start of the procedure and before and after each scan. The temperature changes were only recorded before and immediately after the end of the exposures because the RF energy interferes with the function of the thermistor probe. If the thermistor probe provides a moderate resistance to ground, the thermistor can absorb sufficient energy to become "hot." It was therefore disconnected during the scan. Surface rather than core temperature was measured because more power is absorbed at the surface [6]. The axilla was chosen primarily because of convenience.

Blood pressure and heart rate were measured with an automated monitor that examines arm-cuff pressure oscillations (Bard-Sentry). The respiratory rate was monitored by measuring pressure oscillations in a chest bladder with a low-measure transducer (Validyne). Blood pressure, heart rate, respiratory rate, and temperature were measured at 3-min intervals throughout the study.

The temperature effects of the individual scans were quantified by calculating the difference in temperature before and immediately after the scans. Changes in other parameters were defined as the difference between the last measurements during the scan and the prescan baseline values. Means and standard deviations of these values were calculated for the three power levels and three scan times. The paired Student's *t*-test was used to calculate significance ($p < .05$).

TABLE 1: Volunteer Groups

	Head	Lumbar
Women	10	6
Men	3	8
Age (range)	34–87	22–60
(mean)	59.1	34.4
Weight (range)	125–190	120–225
(mean)	163	160

Results

The 27 volunteers who participated in this study were divided into two groups: head and lumbar (Table 1). The 13 volunteers in the head group were predominantly women, and this group was older than the lumbar group. The mean weight was approximately the same in the two groups. As shown in Table 2 all of the changes we observed were small and well within the range of normal daily variations.

TABLE 2: Mean Changes vs Power Level (with Standard Deviations)

	Watts/kg	TEMP*	BP	HR	RR
		°C	mmHg	BPM ¹	BPM ²
Lumbar Group	0.0	0.1 \pm 0.1	0 \pm 0.4	0 \pm 1.4	0 \pm 0.4
	0.2	0.2 \pm 0.1	–2 \pm 1.4	0 \pm 1.1	0 \pm 0.4
	0.8	0.5 \pm 0.1	–1 \pm 1.5	3 \pm 1.3	0 \pm 0.5
Head group	0.0	0.1 \pm 0.01	–2 \pm 2.2	0 \pm 0.9	0 \pm 0.6
	0.02	0.2 \pm 0.1	4 \pm 2.2	1 \pm 0.8	1 \pm 0.6
	0.06	0.1 \pm 0.01	–5 \pm 3.3	–3 \pm 0.9	1 \pm 0.5

Note.—TEMP = temperature, BP = blood pressure, HR = heart rate, RR = respiratory rate, BPM¹ = beats per minute, BPM² = breaths per minute.

* Mean temperature changes have been rounded to the nearest 0.1° C while other parameters were rounded to the nearest integer.

Lumbar Group

In the lumbar group, the mean increase in temperature was 0.1°C for the control scan, $0.2 \pm 0.1^{\circ}\text{C}$ for the 0.2 W/kg scan, and $0.5 \pm 0.1^{\circ}\text{C}$ for the 0.8 W/kg scan (Fig. 1). The

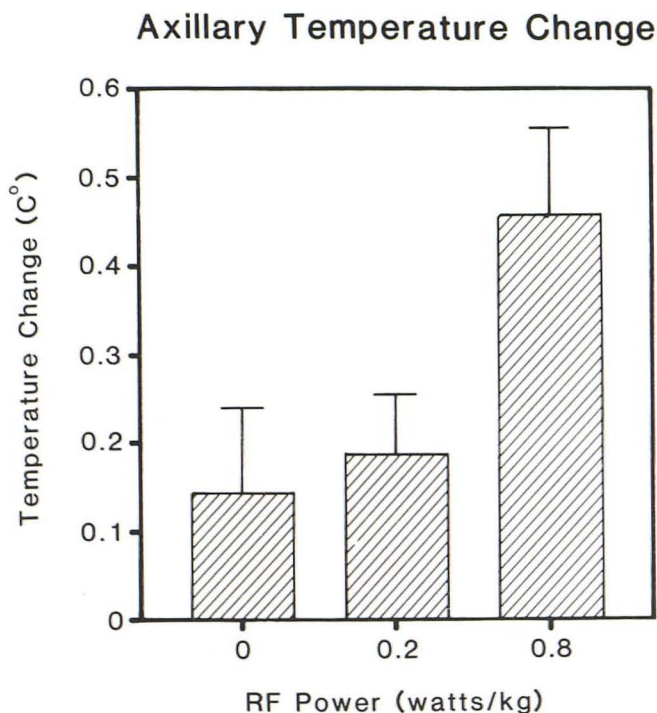


Fig. 1.—Axillary temperature changes in individuals who received lumbar MR.

mean temperature increases with the 0.2 W/kg and the 0.8 W/kg scans were statistically significant. As illustrated in Figure 2 there was a trend for greater temperature increases in lighter individuals as compared with heavy individuals.

Increases in heart rate were small and not significant in the control or 0.2 W/kg scans, while at 0.8 W/kg a statistically significant mean increase of three beats per minute was observed (Table 2). No significant changes in blood pressure and respiratory rate were observed.

Head Group

In the head group, the mean temperature rise was always less than 0.2°C and did not correlate with power level (Table 2). The mean heart rate did not increase during the control and 0.02 W/kg scans. However, during the 0.06 W/kg scan, the heart rate decreased significantly by more than three beats per minute. The mean blood pressure changes during the three scans varied up to 5 mm Hg but were not statistically significant. Respiratory rate varied by less than one breath per minute.

Temperature and other physiologic changes were also examined as a function of scan sequence instead of RF power (Table 3). No significant sequence-dependent physiologic changes were observed for either the head or lumbar groups and the only significant change in temperature occurred during the first lumbar scan.

Discussion

MR safety concerns can be related to the static magnetic field, the changing magnetic field, and the RF power deposition [4]. The only well-established consequence of RF expo-

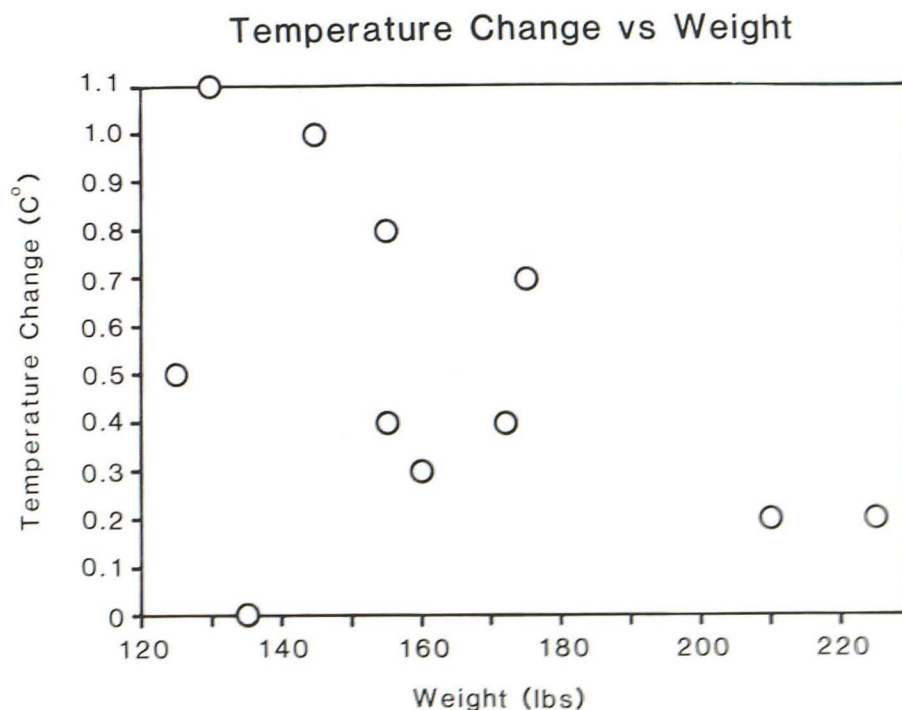


Fig. 2.—Relationship between temperature change and body weight in individuals who received lumbar MR (0.8 W/kg).

TABLE 3: Mean Changes vs Scan Sequence (with Standard Deviations)

	Scan Order	TEMP*	BP	HR	RR
		°C	mmHg	BPM ¹	BPM ²
Lumbar Group	1	0.5 ± 0.4	-2 ± 5.2	0 ± 5.5	0 ± 1.5
	2	0.2 ± 0.3	-1 ± 5.8	2 ± 4.5	0 ± 1.6
	3	0.1 ± 0.3	2 ± 4.9	2 ± 4.4	0 ± 1.6
Head Group	1	0.2 ± 0.4	0 ± 6.1	-2 ± 3.8	0 ± 2.4
	2	0.1 ± 0.1	-3 ± 12.8	-1 ± 2.7	0 ± 1.8
	3	0.0 ± 0.1	0 ± 10.1	0 ± 4.1	1 ± 1.7

Note.—TEMP = temperature, BP = blood pressure, HR = heart rate, RR = respiratory rate, BPM¹ = beats per minute, BPM² = breaths per minute.

* Mean temperature changes have been rounded to the nearest 0.1° C while other parameters were rounded to the nearest integer.

sure is the absorption of heat by the body. This article is concerned with temperature and other physiologic changes that might indicate that the body's thermoregulatory system has been stressed by the increased power deposition.

The small changes we observed in temperature, heart rate, blood pressure, and respiratory rate suggest that the FDA RF power deposition guidelines can be exceeded by a factor of two in the body without any clinically significant physiologic effects. In fact, the physiologic changes that we observed were within the limits that nonstressed individuals experience each day. The number of volunteers that we studied was small but the results are consistent with another study in which RF power deposition went up to as high as 4.0 W/kg [3].

Based on our results, our institutional review board for patient studies permits MR scans to be performed at RF power levels between 0.4 W/kg and 4 W/kg on patients who are part of a research protocol. All patients are monitored for heart rate and blood pressure while they are in the scanner. In our protocols an increase in heart rate of 20 beats per minute or a change in blood pressure of 20 mm Hg are indications to halt the scan and give the physician an opportunity to evaluate the patient and determine if the study can continue safely. These values were recommended by an ad hoc committee of the Committee on Investigations Involving Human Subjects, which was formed to examine the biological effects of high field strength MR on humans. Scan time is limited to 20 min since patients find it difficult to remain motionless for longer periods and because studies with microwave radiation have shown that short exposure times limit neuroendocrine responses in laboratory animals [7, 8].

In our normal volunteer groups we observed no physiologic changes of clinical significance at RF power levels of 0.8 W/kg. Although we believe that the same will be true at higher RF power levels in normal volunteers and in most patients, we still advise careful observation of these individuals. In addition, we feel that patients with severe cardiovascular compromise and occluded vessels should also be observed, since their ability to exchange heat with the rest of their body will be compromised.

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