Safety of 17O and 23Na MR Imaging of the Human Brain at 9.4 Tesla

I. C. Atkinson[1], R. Sonstegaard[1], L. Bityou[2], N. H. Pliskin[2], and K. R. Thulborn[1]
[1]Center for MR Research, University of Illinois- Chicago, Chicago, IL, United States, [2]Psychiatry, University of Illinois- Chicago, Chicago, IL, United States

Purpose: As ultra-high field MR imaging continues to develop, human subjects are being imaged in static magnetic fields that exceed the current FDA 8 Tesla guideline for insignificant risk MR devices. We have previously reported on the safety of human sodium MR imaging performed at 9.4T [1]. Those initial results are extended here, with the results of an investigation of the safety of 23-sodium (23Na) and natural abundance 17-oxygen (17O) MR imaging at 9.4T.

Methods: Ten healthy volunteers were recruited to participate in this IRB and FDA approved study. Vital signs (heart rate, breathing rate, peripheral arterial oxygenation, end-tidal CO2, blood pressure, and skin temperature) were measured using an MR-compatible patient monitoring system (Invivo Corp., Orlando, FL) and cognitive performance (memory and attention) was measured using standard neuropsychological tools (see **Table 1**) according to the data collection schedule shown in **Figure 1**. Each cognitive testing session lasted approximately 30 minutes. The MR imaging consisted of a total of 60 minutes of imaging. 23Na imaging at 105.92 Mhz lasted typically 20-30 minutes and natural abundance 17O imaging at 54.25 MHz took typically 30-40 minutes. All imaging was completed at 9.4T and performed within the FDA guidelines for SAR and gradient switching.

The vital sign and cognitive performance data were analyzed using a two-way analysis of variance (ANOVA) with repeated measures to test for statistically significant changes due to magnetic field (< 0.5 mT, 0.3T, 9.4T) or time (before imaging, between 23Na and 17O Imaging [vitals only], after imaging).

Results: Nine subjects completed the FDA and IRB approved protocol without incident; one subject withdrew due to claustrophobia after being placed in the RF coil but before entering the magnet room. The most commonly reported sensation (5 volunteers) was vertigo when being moved through the magnetic field. The p-values for the two ANOVA factors are shown in **Table 1** and the data from the five p-values less than 0.05 are shown in **Figure 2.**

Table 1: P-values from statistical analysis

Vital Sign	Time	Magnetic Field
Pulse Rate	0.959	0.465
Systolic Blood Pressure	0.078	0.084
Diastolic Blood Pressure	**0.041**	**0.005**
Respiratory Rate (N=9)[A]	0.481	0.925
O_2 Saturation	0.136	0.764
End-Tidal CO_2 (N=9)[A]	0.063	0.710
Skin Temperature	0.125	**< 0.001**
Cognitive Test	**Time**	**Magnetic Field**
HVLT-R Total	0.407	0.178
HVLT-R Delay	0.668	0.516
HVLT-R Recognition	>0.99	0.170
BTA Numbers	0.314	0.458
BTA Letters	0.762	0.924
Digit Span	**0.047**	0.526
Letter Number Sequencing	0.171	0.440
PASAT	0.072	**< 0.001**

[A]One subject censored from analysis due to breathing through mouth instead of nose, leading to inconsistent respiratory and ETCO2 data from the nasal sensor.

The cognitive data in **Figure 2** show that both the individual and average PASAT (paced audio serial addition task) scores increase with increasing magnetic field exposure, indicating a practice effect rather than a true magnetic field effect. Subjects performed poorest during the first session, presumably before developing a strategy for completing the PASAT test. A similar practice effect is present in the digit span test, where performance increased slightly over time in both individual subjects and the averaged data.

The skin temperature data shows a general trend of decreasing temperature with magnetic field exposure. Noting that the concern would be **increased** temperature due to RF heating, the decrease in temperature does not represent a safety issue. The temperature change is likely due to the magnet room being approximately 3°C cooler than the area outside the magnet room. Because the data collection is balanced and subjects begin and end the protocol outside the magnet room, there was no average temperature change over time. The mean subject temperature immediately before imaging (34.5 ± 0.8°C) and immediately after imaging (34.6 ± 0.5°C) was within the precision of the temperature probe (0.1°C). The apparent dependence of diastolic blood pressure on both magnetic field exposure and MR imaging is a small change and likely a false positive due to the wider biological variation across subjects.No dependence of blood pressure on magnetic field exposure was found in our previous investigation [1] or has been reported by other researches working at ultra-high magnetic field strengths.

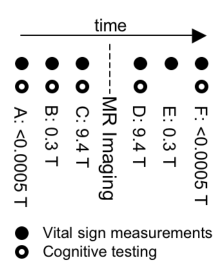
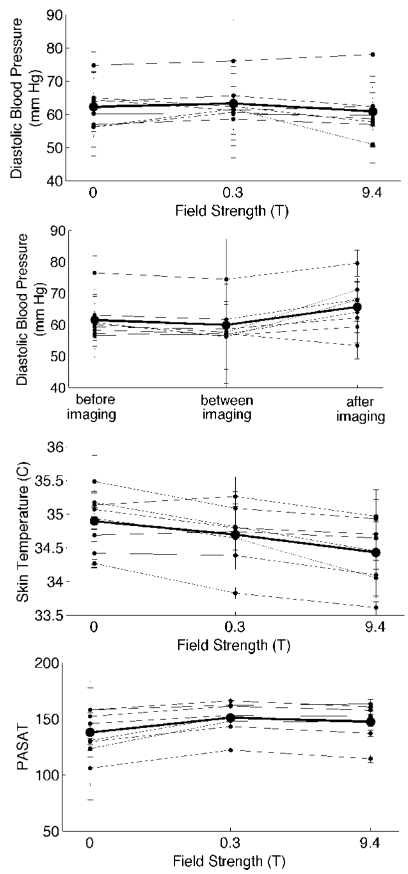


Figure 1: Data collection



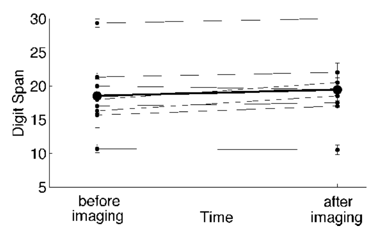


Figure 2: Plots of data from each subject (thin lines) and average (thick line) for the five measurements with statistically significant p-values (p-value < 0.05). The mean (dot) and standard deviation (std error) of each subject are indicated. Note that "before imaging" includes the data collected at < 0.5 mT, 0.3T, and 9.4T before imaging was performed, "between imaging" includes the data collected between 23Na and 17O imaging (vital signs only), and "after imaging" includes the data collected at < 0.5 m T, 0.3T and 9.4T after imaging was completed.

Conclusion:
Vital sign and cognitive performance data collected before, during, and after support the hypothesis that that 23-sodium and 17-oxygen MR imaging of the human brain can be performed safely at 9.4T.

References: [1] I. C. Atkinson, L. Renteria, H. Burd, N. H. Pliskin, and K. R. Thulborn. "Safety of human MRI at static fields above the FDA 8T guideline: sodium imaging at 9.4T does not affect vital signs or cognitive ability." JMRI. 2007; 26:1222-1227.