Effect of 9.4 Tesla Sodium MR Neuroimaging on Vital Signs and Cognitive Performance in Healthy and For-Cause Volunteers

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Purpose:

Novel applications of ultra-high field magnetic resonance (MR) imaging continue to drive MR imaging of humans above the FDA 8 Tesla (T) static magnetic field insignificant risk guideline. Four 9.4 T human MR scanners now exist, as well as a growing number of commercial 7 T scanners that fall within the FDA guideline. Human subjects, including for-cause volunteers (patients with established diagnoses), are increasingly exposed to ultra-high static magnetic fields. We have previously reported on the effect of 9.4 T MR imaging on healthy adults[1,2]. Those results are now extended with the first 9.4 T safety data on for-cause subjects and additional results on healthy volunteers.

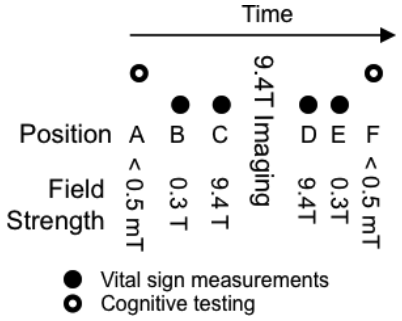

Figure 1: Data collection

Methods:

Twenty (20) healthy and twenty (20) for cause-volunteers (brain tumor, migraine, electrical trauma, traumatic brain injury, and depression) were recruited into this IRB and FDA approved investigation. Vital signs (heart rate, breathing rate, peripheral arterial oxygenation, end-tidal CO2, and blood pressure) 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**) before and after 9.4T non-proton imaging according to the data collection schedule shown in **Figure 1**. The PASAT-200 was administered once (randomly before or after imaging) to each subject to avoid the known practice effect. All other cognitive tests were given before and after imaging with appropriate use of alternate forms to avoid practice effects. Imaging included a combination of 9.4 T sodium, oxygen, and phosphorus imaging performed at frequencies below 165 MHz in less than 60 minutes and within the FDA guidelines for SAR and gradient switching.

A two-way analysis of variance (ANOVA) with repeated measures was used to analyze the vital sign data for statistically significant changes due to the magnetic field (0.3T vs 9.4T) or 9.4T imaging (before vs after imaging). The PASAT-200 results were analyzed with a one-way ANOVA for statistically significant changes due to 9.4T imaging. All other cognitive results were analyzed with a one-way ANOVA with repeated measures statistically significant changes due to 9.4T imaging.

Table 1: Statistical analysis of cognitive testing before & after 9.4T Imaging. No statistically significant changes were found.

	N		9.4T Imaging (p-value)	
Assessment	Healthy	For Cause	Healthy	For Cause
HVLT-R	20	20	0.572	0.360
SDM-Oral	20	20	0.457	0.218
SDM-Written	20	20	0.569	0.456
LNS	20	20	0.109	0.150
PASAT-200	20	20	0.575	0.259

Results and Conclusion:

All subjects completed the protocol without incident. Technical problems limited vital sign collection in a minority of subjects. The most common issue was inaccurate respiratory/$ETCO_2$ data due inconsistent breathing through the nose. The most commonly reported sensations were vertigo or lightheadedness when being moved through the magnetic field (healthy=13, for-cause=3), nervousness about being imaged (healthy=3, for-cause=5), and sleepiness (healthy=8, for-cause=8). No subject reported any sensation persisting once stationary inside the magnet or outside the magnetic field. After accounting for multiple comparisons, the vital sign or cognitive performance measurements do not reach statistical significance at a 95% confidence level. Individually, three vital sign measurements were found to have p-values less than 0.05. Inspection of the raw data from these three cases revealed no clinical significant safety concerns (i.e., reduced systolic BP after imaging of for-cause subjects; less than a 0.5% change between 0.3 mT and 9.4T in the O_2 saturation of healthy subjects; average $ETCO_2$ of for-cause subjects increased from 33.4 mm Hg to 37.1 mm Hg from before to after imaging).These results support the finding of previous ultra-high field safety studies that 9.4T MR imaging of the brain within the current FDA guidelines for SAR and gradient switching can be performed safely in both healthy and for-cause subjects without any readily demonstrated changes in vitals signs or cognitive ability.

References: [1] JMRI. 2007; 26:1222-1227.1227. [2] JMRI. 2010; 32:82–87.

Table 2: Statistical analysis of vital sign data before and after 9.4T imaging, between 0.3 and 9.4T exposure and the combination of exposure and imaging at 9.4T.

	N		Imaging (p-value)		Magnetic Field Strength (p-value)		Interaction (p-value)	
Vital Sign	Healthy	For Cause	Healthy	For Cause	Healthy	For Cause	Healthy	For Cause
Pulse	18	18	0.232	0.194	0.405	0.291	0.147	0.083
Systolic BP	20	19	0.237	**0.006**	0.463	0.073	0.301	0.082
Diastolic BP	20	19	0.479	0.225	0.343	0.076	0.163	0.202
Respirations	19	17	0.397	0.520	0.985	0.988	0.918	0.059
O_2 Saturation	18	18	0.173	0.707	**0.019**	0.544	0.383	0.974
End-Tidal CO_2	19	16	0.724	0.082	0.529	**0.001**	0.414	0.307