A prospective, Randomized, Blinded Study of MultiHance® on 1.5T and 3.0T Strength Field: An Evaluation of Brain, Optic Nerve and Spinal Cord Protocols in Multiple Sclerosis Patients

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OBJECTIVE: To investigate differences in detecting the number, volume and activity of contrast enhancing lesions (CELs) in the brain, spinal cord and optic nerve of patients with multiple sclerosis (MS), using gadobenate dimeglumine (Gd-BOPTA), Bracco Imaging, MultiHance® on 1.5T and 3.0T scanners.

BACKGROUND: It has been hypothesized that the use of 1.5T and 3.0T strength-fields may influence the benefit of contrast agents with high relaxivity, such as MultiHance in detecting CELs. Although the benefit of MultiHance over other conventional contrast agents has been demonstrated at both 1.5T and 3.0T in MRI of brain tumors, intra-individual comparisons of MultiHance at 1.5 and 3.0 T in imaging of central nervous system (CNS) diseases have not been carried out so far.

METHODS: This was prospective, randomized, cross-over, blinded study that included 86 relapsing-remitting (RR) MS patients who underwent brain MRI exam, 53 RRMS patients who obtained spinal cord MRI exam and 40 RRMS patients who obtained optic nerve MRI exam at both 1.5T and 3.0T strength field scanners. All patients were randomized to obtain first scan on 1.5T or 3.0T scanners (1:1 randomization) with second MRI scan being performed within 72-96 hours interval from the first scan. The same scanning protocol was applied at two scanner field strengths (1.5T and 3.0T) after administration of MultiHance 0.1 mmol/kg body weight (injection, 529 mg/mL) with 5 min delay between injection and scanning. All MRI analyses were conducted in a blinded manner. The number of CELs has been identified on 1.5T or 3.0T scanners by a region of interest (ROI) approach for all brain, spinal cord and optic nerve scans. To evaluate volumetric brain differences in CEL detection between 1.5T and 3.0T brain MRI scans, we first performed a simple voxel-wise comparison. Using coregistered 1.5T and 3.0T images and ROIs, we identified those voxels classified as CELs on 1.5T only, on 3.0T only, or on both 1.5T and 3.0T, and produced binary maps in the halfway-space between the two images. We then calculated the total CEL brain volume for each map. In addition, we evaluated CEL-by-CEL brain activity differences between scanners using an in-house developed semi-automated lesion activity analysis (SALA) software tool. We evaluated how many new and/or newly enlarging lesions were found between 1.5T and 3.0T or between 3.0T and 1.5T brain MRI scanners. The CEL differences between the scanners were tested using the McNemar test and Wilcoxon-rank sum test.

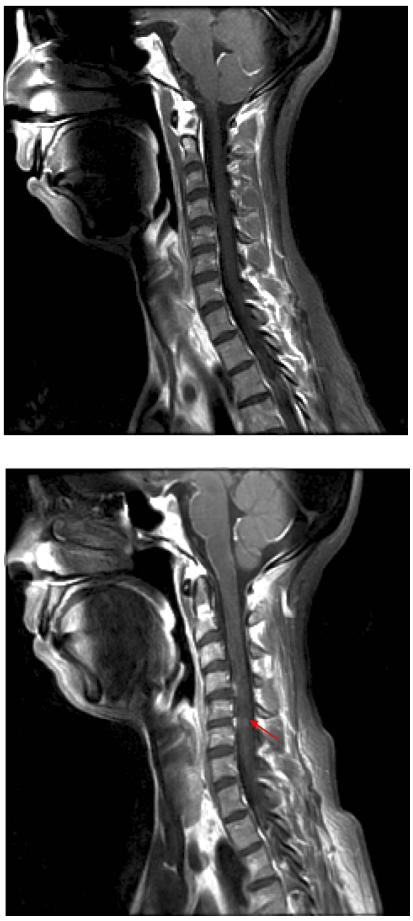

Figure 1: The top image represent T1-post contrast spinal cord scan on 1.5T and 3T (bottom). The contrast enhancing lesion is visible on 3T. but not on 1.5T.

RESULTS: In total, there was 38 brain CELs identified on 3.0T and 30 brain CELs on 1.5T scanner (p=.071). The total CEL volume was also higher on 3.0T compared to 1.5T (p=.086), as well as on 3.0T-only compared to 1.5T-only. In total, SALA identified 12 new and/or newly enlarging lesions between 1.5T and 3.0T scans compared to no new CELs between 3.0T and 1.5T scanners (p=.026). More patients (10) experienced CEL activity on 3.0T brain MRI then on 1.5T (7). In total, 20 CELs were identified on 3.0T spinal cord MRI compared to 11 CELs on 1.5T (p=.083). Thirteen patients showed spinal cord CEL s on 3.0T compared to 8 patients on 1.5T. In total, 5 CELs were identified on 3.0T optic nerve MRI compared to 4 CELs on 1.5T (p=NS). Four patients showed optic nerve CEL s on 3.0T compared to 3 patients on 1.5T. No safety issues were reported, except one episode of nausea without vomiting on 1.5T scanner and with projectile vomiting on 3.0T scanner that occurred in the same MS patient.

CONCLUSIONS: This study shows that the use of a high relaxivity contrast agent, such as MultiHance at 3.0T field strength increases the diagnostic benefit in detecting CELs when compared intra-individually to the application of the same agent at 1.5T. In fact, significantly higher number of new and/or enlarging CELs was identified on 3.0T compared to 1.5T brain MRI and there was a trend for higher number of CELs on 3.0T spinal cord MRI. In addition, higher number of individual patients presented CEL activity on the brain and spinal cord 3.0T scanner compared to 1.5T.