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Original contribution

Quantitative quality assurance in a multicenter HARDI clinical trial at 3 T

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ABSTRACT

A phantom-based quality assurance (QA) protocol was developed for a multicenter clinical trial including high angular resolution diffusion imaging (HARDI). A total of 27 3 T MR scanners from 2 major manufacturers, GE (Discovery and Signa scanners) and Siemens (Trio and Skyra scanners), were included in this trial. With this protocol, agar phantoms doped to mimic relaxation properties of brain tissue are scanned on a monthly basis, and quantitative procedures are used to detect spiking and to evaluate eddy current and Nyquist ghosting artifacts. In this study, simulations were used to determine alarm thresholds for minimal acceptable signal-to-noise ratio (SNR). Our results showed that spiking artifact was the most frequently observed type of artifact. Overall, Trio scanners exhibited less eddy current distortion than GE scanners, which in turn showed less distortion than Skyra scanners. This difference was mainly caused by the different sequences used on these scanners. The SNR for phantom scans was closely correlated with the SNR from volunteers. Nearly all of the phantom measurements with artifact-free images were above the alarm threshold, suggesting that the scanners are stable longitudinally. Software upgrades and hardware replacement sometimes affected SNR substantially but sometimes did not. In light of these results, it is important to monitor longitudinal SNR with phantom QA to help interpret potential effects on in vivo measurements. Our phantom QA procedure for HARDI scans was successful in tracking scanner performance and detecting unwanted artifacts.

1. Introduction

Multiple sclerosis (MS) is a chronic disease characterized by inflammatory demyelination of the central nervous system. Ibudilast is an agent that has shown potential neuroprotective efficacy in MS [1]. The Secondary and Primary pRogressive Ibudilast NeuroNEXT Trial (SPRINT-MS), which is being conducted at 28 clinical sites to ensure high patient enrollment and diversity in the study population, is using the NeuroNEXT Network (www.neuronext.org), a National Institutes of Health-sponsored framework designed to facilitate clinical trials of treatment for neurological diseases. If this trial demonstrates that Ibudilast is effective in slowing the progression of atrophy or other advanced imaging measures of neurodegeneration, it would represent a significant step forward in the development of therapy for progressive MS.

SPRINT-MS is using advanced magnetic resonance imaging (MRI) to characterize brain tissue integrity in patients with progressive MS and to correlate imaging measures with clinical activity. The primary outcome of this trial is whole-brain atrophy. A secondary outcome of this trial is change in diffusivity measurements as measured by high angular resolution diffusion imaging (HARDI) [2]. The quantitative nature of HARDI makes it attractive for multicenter clinical trials, as this technique can characterize brain tissue integrity with high granularity and may be useful for measuring the benefit of putative neuroprotective therapies [3]. In the SPRINT-MS trial, change in transverse diffusivity (TD) along the pyramidal tracts is being evaluated as a biomarker for the efficacy of Ibudilast treatment.

Variability among scanners may cancel the benefit of using multiple centers to assess new treatments. These scanner variabilities may be attributed to differences among scanner hardware and software. Previous work demonstrated that comparable fractional

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anisotropy and diffusivity values could be obtained from 5 different 3 T MR scanners and platforms, even with a software upgrade [4]. However, other studies have found that imaging measurements may differ when various models of scanners or scanners from various manufacturers are used [5] or even when the same scanner model is used [6,7]. Therefore, differences among scanners, including differences caused by repairs or upgrades of software or hardware, must be quantified in longitudinal studies. Standardizing protocols, training technologists in scanning techniques and periodically performing quality assurance (QA) for each scanner are essential when attempting to minimize differences among study centers.

A number of artifacts may degrade HARDI image quality and lead to inaccurate quantitative measurements. A minimum signal-to-noise ratio (SNR) is required in diffusion-weighted (DW) imaging to prevent systematic bias in diffusivity values [8]. HARDI sequences require many gradient directions with large durations and amplitudes [9] which, together with the fast switching of gradients in the echo planar imaging (EPI) readout, can provoke spiking artifact more frequently than in conventional imaging [10]. The combination of large diffusion-weighting gradients and low bandwidth (BW) of the EPI readout risks severe geometric distortion due to eddy currents [11]. Because EPI readout uses a zigzag trajectory through k-space, Nyquist ghosting artifacts can also occur on reconstructed images [12].

Although a standard functional MRI (fMRI) QA protocol and criteria have been published [13], there is no universally accepted standard QA procedure for HARDI. Previous multicenter diffusion imaging studies have been limited to scanners from the same manufacturer or to only a few sites [14] or fewer gradient directions [5,15].

In this study, we developed a phantom-based QA protocol for a multicenter HARDI clinical trial using 3 T MR scanners from 2 major manufacturers at 27 imaging sites. We used quantitative procedures to detect spiking and to evaluate eddy current and Nyquist ghosting artifacts. Simulations were used to determine alarm thresholds for minimal acceptable SNR.

2. Materials and methods

2.1. MR scanners

At the beginning of this study, a detailed survey was sent to each site in the NeuroNEXT Network to gather information about the essential features of readily accessible scanners (manufacturer, model, field strength, head coil, software, ability to perform HARDI). A total of 27 MR scanners (11 Siemens TIM Trio, 6 Siemens Skyra, 1 GE Signa EXCITE, 7 GE Signa HDxt, 1 GE DISCOVERY MR750, and 1 GE DISCOVERY MR750W) were approved for inclusion in the study (Table 1). The scanners were manufactured by Siemens (Erlangen, Germany) and GE (Waukesha, WI, USA). The scanners had various software levels (Siemens: VB17 and VD13; GE: 12×, 15×, 16×, 23×, and 24×).

Head coil choice was constrained to limit variability due to sensitivity profiles of the coils. Standard 20-, 12-, and 8-channel coils were required on Siemens Skyra, Siemens Trio, and GE scanners, respectively. However, 1 GE Discovery MR750 site (scanner #1) was limited to a 16-channel (HNS HEAD) coil.

2.2. Site visits

Two MRI physicists visited each site to train the technologists on phantom QA procedures (described below), which were designed to limit variability in scanning the phantom. A healthy control qualifying (HCQ) scan was also acquired at the time of the visit. The protocols can be found in the supplemental material. Both the HCQ and initial phantom qualifying scan had to be approved before the site was allowed to recruit patients.

Table 1
3 T MR scanners involved in SPRINT-MS.

Site	Manufacturer	Model	Software version	Coil
1	GE	DISCOVERY MR750	DV24.0_R01_1344.a	32ch Head/ HNS HEAD
2	GE	DISCOVERY MR750W	DV23.1_V02_1317.c	Head 24/ 8HRBRAIN
3	GE	Signa EXCITE	12.0_M5B_0846.d	8HRBRAIN
4	GE	Signa HDxt	15.0_M4A_0947.a	8HRBRAIN
5	GE	DISCOVERY MR750/Signa HDxt	DV23.1_V02_1317.c/ 15.0_M4A_0947.a	8HRBRAIN
6	GE	Signa HDxt	HD16.0_V0._1131.a	8HRBRAIN
7	GE	Signa HDxt	HD16.0_V0._1131.a	8HRBRAIN
8	GE	Signa HDxt	HD16.0_V0._1131.a	8HRBRAIN
9	GE	Signa HDxt	HD16.0_V0._1131.a	8HRBRAIN
10	GE	Signa HDxt	HD16.0_V0._1131.a	8HRBRAIN
11	Siemens	Skyra	Syngo MR D13	20-channel head–neck array
12	Siemens	Skyra	Syngo MR D13	20-channel head–neck array
13	Siemens	Skyra	Syngo MR D13	20-channel head–neck array
14	Siemens	Skyra	Syngo MR D13	20-channel head–neck array
15	Siemens	Skyra	Syngo MR D13	20-channel head–neck array
16	Siemens	Skyra	Syngo MR D13	20-channel head–neck array
17	Siemens	Trio	Syngo MR B17	12-channel standard Siemens
18	Siemens	Trio	Syngo MR B17	12-channel standard Siemens
19	Siemens	Trio	Syngo MR B17	12-channel standard Siemens
20	Siemens	Trio	Syngo MR B17	12-channel standard Siemens
21	Siemens	Trio	Syngo MR B17	12-channel standard Siemens
22	Siemens	Trio	Syngo MR B17	12-channel standard Siemens
23	Siemens	Trio	Syngo MR B17	12-channel standard Siemens
24	Siemens	Trio	Syngo MR B17	12-channel standard Siemens
25	Siemens	Trio	Syngo MR B17	12-channel standard Siemens
26	Siemens	Trio	Syngo MR B17	12-channel standard Siemens
27	Siemens	Trio	Syngo MR B17	12-channel standard Siemens

2.3. Phantom scans

The BIRN phantom was chosen as the standard phantom for this trial because it is readily available and because its properties match those of brain tissue [13]. Five imaging sites (sites #11, #18, #21, #23, and #27 in Table 1) used their own BIRN phantoms for this trial.