Collaboration of MD-PhD: MRI for drug development

SY27-1

Updates of MR techniques utilized in clinical trials

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Voxel based morphometry(VBM) and functional MRI(fMRI) technique have played an important role in the study of brain structure, function, and network dynamics. The development of many methodologies have created various analytical tools for brain structure and functional study. The quality control of raw data acquisition stage has influence on results of preprocessed data when you do analyses with acquired structural or functional imaging data. My talk introduce real-time prospective motion correction method for brain structure measurement and multi-band EPI method for fMRI study. The prospective motion correction(PROMO)method is able to do real time motion correction scan when you do brain structural scan with subjects who have many movement in the scanner. In this talk, the speaker presents results between measured bran structure data with or without PROMO and suggests a possibility of the PROMO method for brain structure study with moving subjects include longitudinal study. The multi-band technique allows a reduced measurement time by the simultaneous acquisition of multiple slice yielding. The multi-band technique provides higher temporal resolution fMRI data than conventional method. This talk presents a reliability of multi-band fMRI through a comparison between multi-band EPI based resting state fMRI and conventional resting state fMRI.

Keywords : Promo, Mprage, Fmri, VBM

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Imaging management system to use MRI in clinical trials

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In order to use MRI in clinical trials, minimization of imaging process variability is very important to generate reliable imaging results. Standardization of imaging acquisition protocol, anonymizatin/transfer, analysis, and report are mandatory in clinical trials. At least, trial-specific imaging process standards should be achieved and detailed in a trial protocol or image charter. The use of phantoms may be important to evaluate image acquisition standards, depending on the nature of the imaging endpoint. Integrated imaging management system to control image anonymization/transfer, central reading, and analysis enhance efficiency of whole imaging process. Recently, FDA issued a draft guidance for imaging process standards, and many global pharmaceuticals and CROs follow the regulation. We, radiologists and MR physicists, should be aware of these global trends in management of clinical trial imaging.

Keywords : MRI, Clinical Trial, Drug development

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SY27-3

Standardization of MR techniques for clinical trials

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On these days, many MR(Magnetic Resonance) imaging methods are employed for quantification studies, e.g. tumor characterization, fat fraction measurement, relaxivity measurement and so on. However, many researchers provide different imaging parameters and results from their studies. In addition, currently, multi center study is also an important to provide more reliable results. For these reasons, we need to take some standardization to achieve more reliable resutls from future study's datasets to share many things from MR imaging to analysis. For example, DCE(Dynamic Contrast Enhancement) MR imaging already has a kind of standardization from QIBA(Quantitative Imaging Biomarkers Alliance; http://qibawiki.rsna.org) for MR imaging and data analysis. This kind of standardization can provide us more reliable results from different MR scanners. So, we need to set up a standard imaging protocols and image analysis method for the future study.

Keywords : Standardization, QIBA, MRI

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SY27-4

Global trends of regulation to use imaging in clinical trials

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Bioimaging is one of widely used diagnostic tool in clinical trials as it can provide both anatomical and functional parameters. To apply bioimaging-parameters as biomarkers for monitoring the treatment agents, two important factors of surrogate endpoint, ie, validation and qualification, should be satisfied. In this regard, there have been an increasing number of studies demonstrating the limitations of bioimaging parameters as surrogate endpoints. Therefore, in order to improve the application of bioimaging in drug discovery, it is required to establish a standardized evaluation method and to determine the correct therapeutics-oriented meaning of individual bioimaging parameter. In this talk, the global trends of regulation to use bioimaging in clinical trials will be discussed.

Keywords : -