Global Clinical Trials for Alzheimer's Disease: Chapter 9. Standardization of MRI and Amyloid Imaging

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In-vivo imaging markers of neuronal changes related to Alzheimer’s disease (AD) are ideally suited to be employed as diagnostic markers for early and differential diagnosis of AD as well as for the assessment of neurobiological effects of medical treatments in clinical trials. Novel molecular imaging techniques enable in-vivo detection of cerebral amyloid pathology, whereas magnetic resonance imaging (MRI)-based techniques, such as volumetric MRI and diffusion tensor imaging (DTI), provide structural lesion markers that allow tracking disease progression from preclinical through predementia to clinically manifest stages of AD. However, a widespread clinical use of these imaging biomarkers is hampered by considerable multi-centric variability related to differences in scanner hardware and acquisition protocols, but also by the lack of internationally agreed upon standards for analytic design and employed quantitative metrics. Several strategies for reducing multicenter variability in imaging measures have been proposed, including homogenization of the acquisition settings across scanner platforms, stringent quality assurance procedures, and artifact removal by means of post-acquisition image processing techniques. In addition, selection of appropriate statistical models to account for remaining multicenter variability in the data can further improve the accuracy and reproducibility of study results. The first projects for international standardization of image analysis methods and derived quantitative metrics have emerged recently for volumetric MRI measures. In contrast, the standardization and establishment of DTI-derived measures within a multicenter context are less well developed. Although molecular imaging techniques are already widely used in multicenter settings, sources of variability across sites and appropriate methods to reduce multicenter effects are still not explored in detail. Comparability of neuroimaging measures as AD biomarkers in worldwide clinical settings will finally depend on the establishment of internationally agreed upon standards for image acquisition, quality assurance, and employed quantitative metrics.

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