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A Coordinated Method for Clinical Trials Research: Multireader Assessment of MR Imaging Features of Human Gliomas

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PURPOSE

Image based clinical research trials present unique challenges due to nonstandard use of terminologies, absence of uniform data collection & lack of validation. The purpose of this project was to assess reliability of a uniform terminology and tools developed through the Cancer Bioinformatics Grid (caBIG) initiative in a multireader assessment of glioblastoma MR imaging (MRI) features.

METHOD AND MATERIALS

A controlled terminology for describing the MR features of human gliomas was adapted based upon prior work. This comprehensive featureset consists of 24 observations familiar to neuroradiologists to describe the morphology of gliomas on routine contrast-enhanced MRI. De-identified baseline MRI studies for 130 glioblastomas collected for the Cancer Genome Atlas (TCGA) initiative were evaluated. Six neuroradiologists in three disparate geographic locations used a research PACS workstation to annotate and score the cases. Scorings were electronically sent to a central repository for data collection/analysis. A lossless statistical compression methodology for the diagnostic imaging features was employed without any loss of information. Interobserver variation for each feature was assessed with the generalized kappa statistic of Berry & Miekle.

RESULTS

Stepwise compression of multiple MR imaging feature values and validation were performed without loss of statistical information. The results indicated strong overall average interobserver agreement among all six readers. Features with high agreement included proportion enhancing tumor (k=0.656, 95% CI 0.596-0.757), presence of satellites (k=0.663, 95% CI 0.591-0.780), and diffusion (k=0.730, 95% CI 0.664-0.828). Of the remaining, only three features (12.5%) showed low agreement (k<0.4): presence of calvarial remodeling (k=0.366, 95% CI 0.124-0.626), cortical involvement (k=0.167, 95% CI 0.157-0.335), and definition of nonenhancing margin (k=0.374, 95% CI 0.347-0.514).

CONCLUSION

Development, validation and generalized use of controlled terminologies into imaging arms of clinical trials is essential in demonstrating imaging as a biomarker in cross-cutting correlative studies.

CLINICAL RELEVANCE/APPLICATION

Universal use of controlled terminologies/ontologies are imperative in extending the value of imaging as a potent biomarker in clinical research.