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A Methodology for Multi-reader Assessment of MR Imaging Features of Gliomas in Clinical Trials

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Abstract: PURPOSE
Research trials that incorporate imaging present unique challenges due to nonstandard use of terminologies, absence of uniform data collection and validation. These obstacles traditionally limit the impact of imaging as an effective biomarker in oncology. The purpose of this project was to assess reliability of tools and terminology developed by the Cancer Bioinformatics Grid (caBIG) initiative when performing a multireader simultaneous assessments of glioblastoma MR imaging features.
MATERIALS & METHODS
A controlled terminology for describing the MR features of human gliomas was devised based upon prior work

(VASARI/Rembrant project). This comprehensive featureset consists of 24 observations familiar to neuroradiologists to describe the morphology of brain tumors on routine contrast-enhanced MRI. The National Biomedical Imaging Archive (NBIA) was used to store the de-identified baseline MRI studies for 78 glioblastomas collected for the Cancer Genome Atlas (TCGA) initiative. Six neuroradiologists in three disparate geographic locations were recruited and trained in the use of the featureset using a visual guidebook. Training cases were employed to assess competency and to ensure agreement. A open-source PACS workstation (Clear Canvas) was customized for clinical imaging research evaluation and deployed at each of the three centers. Networking tools built into the workstation were used to securely download studies from NBIA (caGRID). As studies were evaluated, scores were simultaneously uplinked to a single remote AIM (Annotation and Image Markup) repository for QC checks and interim analysis. Case assignments were deliberately staged in a staggered fashion to ensure that a minimum of three evaluations were efficiently obtained. Administrative tools were employed by coordinators in a fourth location. Qualitative assessments included: (1) effectiveness of training, (2) ease of deployment & functionality of the informatics solutions and (3) efficiency of the process. Inter-observer variation for each feature was assessed with the generalized kappa statistic of Berry&Miekle.

RESULTS

Training, deployment of resources and completion of three evaluations per case were accomplished in 30 days. Functionality of the IT solutions was rated superior in qualitative assessment. The results indicated strong overall average inter-observer agreement among all six readers. Agreement was highest for tumor side (generalized kappa statistic k=0.943, 95% CI 0.915-0.982) and tumor location (k=0.837, 95% CI 0.807-0.902). Other 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 non-enhancing margin (k=0.374, 95% CI 0.347-0.514).

CONCLUSION

Inclusion of vetted, tested and validated controlled terminologies into imaging arms of clinical trials is essential in adding value of imaging as a biomarker in cross-cutting correlative studies. Controlled terminologies such as the one described herein for assessment of gliomas can be effectively used by domain experts following a relatively short training period. Technologies developed through the caBIG initiative provide an effective and efficient framework for federated imaging assessments that can expedite cross-correlative analysis with other data repositories (e.g. genomics/proteomics/pathology).

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