QIBA Dynamic Susceptibility Contrast (DSC-MRI) Biomarker Committee (BC) Call

Wednesday, February 10, 2021 at 11 a.m. (CT)

Call Summary

RSNA

Participants

Bradley Erickson, MD, PhD (Co-Chair)Michael Boss, PhDNancy Obuchowski, PhDJoe KoudelikOna Wu, PhD (Co-Chair)Lisa Cimino, RTSusan Stanfa

White Paper Plans

- The DSC-MRI BC Google Drive contains the Stage 2 Profile; access can be requested from Dr. Erickson
- Materials related to this effort can be found in the <u>White Paper folder</u> in the DSC-MRI BC Google Drive
- The title is: QIBA Recommendations: Towards dynamic susceptibility contrast MRI-based quantitative imaging biomarkers for multi-center neuro-oncology trials
- The <u>outline</u> was inspired by Dr. Dave's paper, <u>Quantitative Imaging Biomarkers Alliance (QIBA)</u>
 <u>Recommendations for Improved Precision of DWI and DCE-MRI Derived Biomarkers in Multicenter Oncology</u>
 <u>Trials</u>. JMRI. 2019; 49(7): e101-e121
- Writing assignments are documented in the **<u>outline</u>** Google Doc and work is underway
- Discussion re: possible publication for this paper
 - o JMRI and J of NeuroOncology were previously recommended
 - Drs. Boss and Wu strongly encourage submitting to *Radiology*, which recently accepted the MSK paper (effort led by Dr. Chalian)
 - It was noted that RSNA has a vested interest in promoting QIBA activities and the DSC paper may have a good chance of being accepted
- The main focus of the paper is the need for public data to evaluate reproducibility and repeatability of DSC, as there is a dearth of test-retest data; limitations in existing data will also be explained
 - o The need for collection of normative DSC data, across both time and subjects will be reinforced
 - o Both the DSC-MRI Profile, and the community as a whole, would benefit from additional test-retest data
 - o Clinical trial nuances for DSC-MRI to be highlighted
- True coffee break test-retest may be nearly equivalent to a temporal reproducibility study; depending on the results of the ACRIN trial (paper to be submitted to *JMRI*), this idea may be included
 - It was noted that in a coffee break test-retest scenario, patients would be subjected to a double dose of contrast agent within a relatively short period of time (not recommended)

Possible Implementation of DSC-MRI Profile in the GABLE Study

- An ad hoc meeting on this topic with QIBA Leadership and DSC-MRI BC Co-chairs is scheduled for Tuesday, February 16; data needed to help advance the Profile to be determined
- It was stated that since the <u>DSC-MRI Stage 2: Consensus Profile</u> is mature, a pathway to Technical Confirmation (TC) should be explored; a minimum of implementation at three sites is required and corresponding feedback will inform the TC Profile
- It was recommended that DSC-MRI BC Co-chairs urge adherence to the DSC-MRI Profile, so that the GABLE study can be leveraged to collect data that would be used to advance the Profile; the trial would also benefit from the added value of a standardized approach
- Information about the GABLE study protocol is needed
- Discussion re: the use of 1.5T vs. 3T scanners in this study
 - \circ The current DSC Profile focuses on only 3T platforms, which may limit use in this study
 - Suggestion that DSC-MRI BC develop a guidance document for best practices at 1.5T

- While reproducibility will not be as good with 3T, the resulting 1.5T data would still be valuable and the Profile Claim could be expanded to include those numbers
- With 3T, acquisition timing to remain at 1.5 seconds, but cliff angle may need to be increased; there may be a struggle with signal-to-noise
- It was stated that the best quantitative science will need to be balanced with the needs of the trial, e.g., patient accrual and access to participating sites which may benefit from including 1.5T platforms
- 1.5T is not as costly as 3T, and 3T may present compatibility issues for subjects with certain medical implants
- Hope to learn what amount of 3T data and 1.5T data will result from this study
 - Target accrual is ~200 subjects
 - Current DSC-MRI BC Claims are based on a study containing only 33 subjects
- Boxerman JL, et al. <u>Consensus recommendations for a dynamic susceptibility contrast MRI protocol for use in</u> <u>high-grade gliomas</u> was referenced
- QIBA was deemed the premier source for developing standards in terms of bias; competing standardization efforts should be avoided
- Due to possible COI issues, specific software is not recommended in QIBA Profiles; approval of a QIBA COI policy is pending and it will be posted for reference on the QIBA Wiki

Next Steps

- The DSC-MRI BC may consider putting the white paper on hold and shift efforts toward finding a pathway to TC
- Discussion re: whether to focus on expanding the current Profile to include 1.5T, or shifting efforts to planning for a new Profile (most likely to focus on stroke)
 - \circ $\,$ Concern that the field is shifting toward CT for imaging related to stroke
 - o Drs. Erickson and Wu to conduct a literature search for 1.5T
 - If it is determined that the GABLE study is not an appropriate avenue for advancing the Profile to TC, other options to be considered, such as pursuing an investigator initiated R01 grant
 - Including or designing a multi-center test-retest study of both healthy volunteers and patient population for test-retest would address gaps in the data for the existing Profile, however funding would need to be determined
 - Concern that COVID-19 may be a barrier re: the feasibility of scanning healthy volunteers, but perhaps with a timeline that extends into 2022, this will no longer be an issue
 - If applying for a grant, it was recommended that a budget line item and rationale for QIBA administrative support be included
 - QIBA leadership to draft boilerplate language or a template for administrative and statistical support in grant requests, as well as for subcontracts
 - Dr. Obuchowski agreed to participate as a statistical consultant (additional support for designing the study or analyzing data would be needed)
 - Dr. Wu to approach possible co-investigators
 - A letter of support would be requested from QIBA leadership and included in grant submission materials

Next DSC-MRI BC Call: Wednesday, March 10, 2021 at 11 a.m. CT

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