

QIBA Diffusion-Weighted Imaging MR Biomarker Committee (BC) Call

Wednesday, November 11, 2020 at 3 pm (CT)

Call Summary

Participants

Michael Boss, PhD (Co-chair)

Amita Shukla Dave, PhD

Nancy Obuchowski, PhD

RSNA

Susan Stanfa

Dariya Malyarenko, PhD (Co-chair)

Gloria Guzmán, MD, MSc, MPH

Brian Taylor, PhD

Trevor Andrews, PhD

Daniel Margolis, MD

Kei Yamada, MD, PhD

Ishtiaq Bercha, MSc, MSEE

Moderator: Dr. Boss

Review of Previous Call Summary

- The notes from the October 15, 2020 DWI BC t-con were approved as presented

Groundwork on Head and Neck Squamous Cell Carcinoma (HNSCC) Repeatability (Drs. Amaro, Dave and Guzmán)

- A proposal was submitted to QIBA leadership re: conducting a test-retest study of DWI in H&N cancers, specifically HNSCC, to inform an ADC Claim for the DWI Profile
- Dr. Guzmán is the PI of this project, with strong support from Drs. Dave and Malyarenko; the draft application for an RSNA R&E Seed Grant (due in Jan 2021) was reviewed
 - First aim: to evaluate the reproducibility of ADC values using test-retest data
 - Second aim: to compare SUVmax and ADCmean/min values to assess the capability of the new DWI pulse sequence to differentiate post-treatment change from residual or early recurrent tumor
 - Third aim: to assess if DWI can more expediently identify non-responders to treatment
- There was consensus to retitle the application from, “Test-retest DWI data in patients with head and neck cancer,” to, “Precision Diffusion Imaging in HNSCC”
- It was recommended that the focus be on the lack of repeatability data needed to inform the DWI Profile Claim, which may broaden interest and appeal
- A research study, “Optimized Diffusion Weighted Imaging: Comparative Effectiveness with PET/CT in the Evaluation of Post-Treatment Head and Neck Squamous Cell Carcinoma,” based on 25 patients is already underway at the Washington University School of Medicine / Mallinckrodt Institute of Radiology; the intention is to expand it to additional sites as a multicenter project
- A call with Drs. Guzmán, Dave, Boss, Malyarenko and Andrews focusing on additional work to the grant application, will be held prior to the December 17 DWI BC call
- Discussion regarding obtaining letters of support for this study before the holidays
 - While QIBA Leadership support is expected, a draft grant application will be presented to support the letter of recommendation request
 - DWI BC Co-chairs to draft a letter of recommendation as well
 - Dr. Boss to provide a letter template already used for the São Paulo DWI Profile implementation project
- Discussion regarding the instrumental design, including stages of lesions, exact location, and size
 - The study states that, “only measurable disease defined as a primary tumor, a suspicious lesion, and/or an area of post-treatment change measuring at least 0.5 cm in two perpendicular dimensions will be used”
 - It was noted that there could be an issue with resolution if the lesion is smaller than 1 cm
- Dr. Dave volunteered to perform a literature review and assist with writing; page number guidelines were requested
- Dr. Obuchowski offered to provide statistical support by reviewing and consulting as needed

VERDICT Team Data/Collaboration: PCa ADC w SD Results (Drs. Malyarenko, Margolis and Obuchowski)

- Dr. Malyarenko provided a brief summary for those who did not participate in the call with the VERDICT team
- The prospective analysis of data will be used to improve the repeatability study for prostate and achieve a better Claim
- In addition to the current DWI Profile longitudinal claim, the VERDICT team is also interested in cross-sectional (cs) Claims
- Additional discussion is needed on how to plan a prospective study and identify next steps toward the development of a cs Claim through the use of a DRO
 - Suggestion to use urine in bladder with 37 Celsius degrees as a reference to determine ground truth
 - At least three possible bias sources were noted
 - Those related to acquisition parameters and could be mitigated
 - Signal-to-noise
 - Diffusion in prostate is not exponential (magnitude)
 - Suggestion to characterize bias as a percentage
 - Recommendation to use the three factors as independent variables to estimate bias
- The approach will be to use the pertosis DRO, which would provide ranges of parameters, and take a plan back to the VERDICT team
- There are implications not only for prostate, but other organ systems
- The VERDICT team to determine how to approach scanning on subjects (building a model) with input from the QIBA DWI BC
- Dr. Malyarenko to reach out to the VERDICT team with suggestions prior to the meeting scheduled for December 11

Possible Guidance Documents (Dr. Boss)

- The QIBA leadership and Process Cmte have been discussing how to define these guidance documents, which are not Profiles but similar to best practice recommendations
- Discussion needed to differentiate these documents from Profiles; they are appropriate for evolving topics (e.g., COVID-19 imaging)

DWI Profile (Dr. Boss) – feedback to be sought as a first step toward Stage 3: Technical Performance

- General QIBA feedback has indicated the need for QIBA groups to shorten Profiles; aiming for brevity and user-friendliness will facilitate the adoption of QIBA Profiles by interested parties, e.g., clinical trials, CROs, etc.
 - Issue with length specifically related to the number of organ sites included in the DWI Profile cannot be resolved
 - Sections of the DWI Profile are quite detailed; it is not necessary to address in the body of the Profile, every possible issue that may emerge
 - Main Profile focus needs to be narrowed and material moved into the Appendices
- Next steps for the DWI Profile include pursuing Technical Confirmation, which is organ-independent and can be established with a phantom; the two conformance tests performed by Invicro and the Brazil consortium are sufficient to advance the DWI Profile
- Additional feedback to be sought from sites that have used the Profile, specifically, recommended changes to the Profile that would facilitate future implementation
 - Suggested process would be to solicit comments, record feedback, propose resolutions and make Profile changes if needed

- Because Invicro has already provided input via materials submitted as part of conformance testing and a presentation during the Sept. QIBA Annual Meeting, it was recommended that they not be solicited for more information
 - Suggestion to review materials already on hand, identify a few main points, put them into a resolutions document, and ask Invicro contacts whether anything that should be added
- Since the São Paulo team did not submit a conformance testing report (only a general project report to the RSNA R&E Dept.), Dr. Boss will provide them with a comment template and request feedback
- Input to be used to refine the DWI Profile

Next DWI-MR BC Call: Thursday, December 17, 2020 at 2 pm (CT)

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