

QIBA PET Myocardial Blood Flow (MBF) Biomarker Committee (BC)

Monday, June 28, 2021, at 9 am CT

Call Summary

Additional notes provided by Dr. Moody

In attendance

Robert deKemp, PhD (Co-Chair)

Marcelo Di Carli, MD (Co-Chair)

Jonathan B. Moody, PhD (Co-Chair)

Michael Boss, PhD

RSNA Staff

Joe Koudelik

Julie Lisiecki

Moderator: *Dr. deKemp*

Discussion

- Dr. deKemp provided an overview of the draft of Steps 0-3 towards the PET MBF Profile (referring to the claim guidance document)
- Since some graphs did not provide enough subject-level data, the RPP data for stress flow will not be adjusted – only the resting state data will be adjusted
- Updated subject-level spreadsheet was sent to Dr Obuchowski on 6/20, including
 - RPP-adjusted rest MBF
 - a new variable “stressor.2” with reduced number of levels (four vasodilators are combined in one level)
 - a new variable “pet.dim.crystal” with 2 levels combining “pet.dim” and “pet.crystal”
 - “Rpp.corr” values were corrected for Byrne stress MBF and MFR data (T -> F)
- Focus will be on vasodilators (stressor.2) for the claim, which will be adjusted per the modeling data to be provided by Dr. Obuchowski
- Both a cross-sectional and a longitudinal claim will be included in the Profile with a wCV metric (within subject coefficient of variation)
- Dr. Di Carli suggested patient management as a primary focus, keeping in mind the diagnosis of obstructive coronary artery disease
- Consistent thresholds are needed, with some consensus or a gold standard
- Approximately 90% of the work will be focused on the cross-sectional claim (clinical relevance), though a longitudinal claim will be included to quantify changes over time
- Dr. Di Carli suggested adding “at rest” and “during stress” as categories for evaluation of coronary vasomotor function under baseline conditions and vasodilator-induced hyperemia
 - Identification of low and high-risk patients to categorize measurements and inform medical decisions
 - This will enable risk-based decisions for patient management
 - While technical performance is important in making an accurate measurement, the patient management, i.e., clinical use-case, is equally important for this Profile
- Dr. Boss noted that the cross-sectional measurement and its dependability will be based on test-rest studies and ground truth, if available
 - To aid in clarifying focus, ask questions such as:
 - Why are we measuring this biomarker?
 - For what purpose will this biomarker be used?
 - Some bias will be added, with the focus on the wCV measurement
- A possible sub-claim for heart transplant patients was discussed
 - wCV will be analyzed in a cohort of heart transplant patients at University of Michigan with serial PET
 - if the wCV is similar to the published test-retest studies, transplant patients could provide validation data at other PET sites
 - if the wCV is higher than published test-retest studies, the analysis may support a claim for this subpopulation

Action items:

- Dr. deKemp to look for methodology papers to support the cross-sectional claim (based on bias and precision)
- RSNA staff to ask Dr. Obuchowski if she can be available for a 7/26 meeting

Next Call: July 26, 2021, at 9 am CT (2nd and 4th Mondays) at 9 am CT

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