

QIBA Proton Density Fat Fraction Biomarker Committee (PDFF BC) Call

Thursday, November 5, 2020 at 3 p.m. (CT)

Call Summary

Participants

Takeshi Yokoo, MD, PhD (Co-chair)

Scott Reeder, MD, PhD (Co-chair)

Mustafa Bashir, MD

Nancy Obuchowski, PhD

J.M. (Hans) Peeters, PhD

Jonathan Riek, PhD

Gary Schooler, MD

Suraj Serai, PhD

RSNA

Joe Koudelik

Susan Stanfa

Review of Previous Call Summary

- The 07.02.2020 call summary was approved as presented

Introduction of New Member (Dr. Yokoo)

Gary Schooler, MD (UT Southwestern Medical Center) was introduced as a new member of the PDFF BC

Updates (Dr. Yokoo)

- Dr. Yokoo is awaiting a response from *Radiology*, after submitting a revised version of the manuscript on the round-robin project (provisionally accepted)
- Now that knowledge gaps have been illuminated by the Calimetrix phantom studies and reference standards can be incorporated, efforts will be shifted to Profile-writing

Discussion focused on “Open Issues” section of the Profile

1. Should conformance tests (phantoms, volunteers) be required or recommended? If so, what kind of phantoms (e.g., zero phantom, 0 vs. 100% phantom, linearity phantom)?
 - Conformance testing is required for vendors developing a new PDFF technique
 - For PDFF products that have been vetted by the vendors, the users are not required to repeat conformance testing, as long as the pulse sequences are used according the vendor’s specifications, unless otherwise recommended by PDFF Biomarker Committee
 - Due to a conflict of interest as founder of Calimetrix, Dr. Reeder recused himself from the discussion/consensus process regarding whether to require commercial phantoms for conformance testing
 - Conformance testing includes linearity and bias testing using a validated triglyceride-based PDFF phantom, covering a typical range of PDFF values (PDFF=0 is required; ≥ 5 vials minimum up to 40% or above)
 - Bias testing must be done against known fat fraction values calculated based on proton-density (i.e. PDFF), rather than some other fat fraction values such as volume- or weight-based
 - Methods of phantom constructions were previously described (PMID:19856457)
 - A commercial PDFF phantom is available
 - MR spectroscopy or other QIBA-conformant MRI-PDFF method could be used as an adjunct to verify the phantom’s PDFF values
 - Conformance testing includes a repeatability study in human subjects
 - The subject cohort should be representative of the target patient population of intended use, e.g. known or at risk of NAFLD/NASH with typical PDFF distribution (PMID:28892458)
 - Per Dr. Obuchowski, sample size of the test-retest study should be at least 35 subjects so that 95% confidence intervals of the repeatability coefficient are within X% (PMID: 29298603)

- 2. Include latest technical development, e.g., Compressed sensing, non-Cartesian, free-breathing acquisitions?
 - Until verified by conformance testing, there is not enough evidence to include it
- 3. Include all variations of PDFF implementations (mono- vs. bi-exponential T2*, T1-independent vs. T1-correction, bipolar vs. monopolar, interleaved echo trains, partial echo)?
 - Details of technical implementation are not specified, as long as the technique controls or corrects known confounders and the performance is validated by conformance testing (linearity, bias, and repeatability)
- 4. Fasting vs. non-fasting prior to scanning: requirement / recommendation
 - There is not enough evidence to require fasting for the purpose of liver fat quantification (PMID:31168893), however, other concurrent imaging procedures (e.g. MRE) may require 2+ hour fasting
 - Dr. Reeder referenced a few papers on this topic and details will be distributed

Action items

- Open Profile Issues and summary of discussions to be distributed by Dr. Yokoo to PDFF BC members for feedback; discussion will continue during the next PDFF BC meeting
- Due to the RSNA Annual Meeting (Nov. 29 – Dec. 5), there will be a one-time shift of the Dec. call date from the first Thursday of the month, to the second
- Topics to be discussed during the December 10 PDFF BC meeting:
 - Open Issue 5: Other recons (R2*, B0, IP, OP, W, F) and how they are used
 - Open Issue 6: How PDFF reporting should be done - research / clinical; relevant references include: Campo/Reeder (PMID: 28705058) and Vu/Tang (PMID: 26536609) on PDFF ROI drawing and reporting
 - If longitudinal measurements are made, colocalized ROIs could be required

Next QIBA PDFF BC call: Thursday, December 10 at 3 p.m. (CT)

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