

EIBALL: QIBA ASL profile meeting

17:00 CEST, October 10th 2018 – online meeting

Attendees

- Xavier Golay
- Peter Gordebeke
- Luis Hernandez-Garcia
- Henk Jan Mutsaerts
- Nancy Obuchowski
- John Detre
- Cathy Elsinger
- Gudrun Zahlmann
- Daniel Barboriak
- Nic Blockley

Summary

Xavier Golay opens the meeting and thanks all attendees for joining call. The calls on the ASL Profile will now be more regular; every other week. The purpose for this call is to go over the first Profile draft and determine how to move forward with the writing – in particular writing the clinical claims, as well as some technical claims.

Xavier Golay thanks everyone who commented on the Profile so far. The latest version of the Profile is available on Google Docs here:

https://docs.google.com/document/d/1BccQoBy1yPOhcRLq8rG54bXEm6TKIEuYAbeUdaThRTM/edit?usp =sharing

The main point of discussion is the lacking clinical context for the Profile and in particular a proper systematic clinical review of ASL. The question is whether that level of review is needed to make any of the claims in the clinical context.

John Detre advocates for very basic claims that can be easily justified, over complex claims describing too much detail. For example, the claim should state that the perfusion in the brain can be measured, as a fundamental idea. Xavier Golay replies that, in his understanding, claims are usually more precise. For example, a defined increase or decrease happens to a certain level of confidence. Henk Jan Mutsaerts has already done a lot of preliminary work for such claims with test / retest data.

Henk Jam Mutsaerts indicates that the main problem with reproducibility studies is that the subjects were all healthy volunteers. Cerebral Blood Flow (CBF) measurements deteriorate as the patients get

sicker. Xavier Golay adds that his group is currently looking into repeatability with patient data, but it is not sure how valuable that is, or if it can be compared to healthy volunteers to infer lower or upper bounds for the Profile.

John Detre reiterates that such claims might be getting ahead too much. As far as the radiological community is concerned, CBF has a gold standard with ¹⁵O PET. ASL and 15O PET fundamentally measure the same thing, water. The former using T1 decay and the latter using radioactive decay. The Profile is currently proposing to have a better alternative, but it's difficult to substantiate this sufficiently. Perhaps it would be better to claim ASL and ¹⁵O PET are able to measure the same thing, rather than going straight to these performance targets. Daniel Barboriak agrees with this, and would include details about ASL potentially being a better gold standard. However, correlation, reproducibility and context (e.g. healthy volunteers vs. patients) remain difficult areas. Claiming to be a replacement for ¹⁵O PET would high-risk, high-reward. John Detre replies that replacing ¹⁵O PET might be a too strong. Claim they are substitutable might be better.

Nancy Obuchowski understands John Detres overall point regarding the simpler claims, and adds that this would be a qualitative claim, not a quantitative claim. QIBA generally uses performance claims so the bias and precision can be stated. It is also possible to have longitudinal claims, and have both performance and longitudinal claims in the same profile. In this case, perhaps a single performance claim would be better.

Xavier Golay thinks the comparison to ¹⁵O PET is interesting. There are multiple papers on the comparison. These could be systematically reviewed to give information on repeatability and reproducibility.

Gudrun Zahlmann states that it is important to have the claim set. The group needs to agree on a small number of papers to review to develop the claim. The clinical context will then follow, as it is more about why ASL is relevant as a quantitative biomarker and not about the performance.

Luis Hernandez-Garcia mentions that results are quite reproducible across vendors and systems and that is may be interesting to include this. Nancy Obuchowski responds that this can be (part of) a basic performance claim.

Xavier Golay indicates he would like a few people to discuss this further outside of this call, and come up with quantitative claims.

Xavier Golay asks whether Bolus Arrival Time (BAT) is suited. John Detre replies that it is tricky, and it may be too much to also include and define a second quantitative biomarkers. John Detre prefers to see Claim 3 of the draft modified to include a prolonged transit time. Reduced CBF might impact BAT, and it is very dependent on how it is measures. Luis Hernandez-Garcia agrees that BAT might be too difficult.

Xavier Golay moves on to clinical interpretation. The starting point is in the current draft, but needs to be revised. The possible applications of ASL in different diseases needs to be included. Some are already mentioned, but may not be in-depth enough. Henk Jan Mutsaerts strongly suggest to keep performance claims and qualitative clinical claims as separate as possible. Gudrun Zahlmann agrees. The focus for the claims and Profile should be on diseases where the quantitative nature of ASL can be used.

Henk Jan Mutsaerts asked how often Profile are updates. Gudrun Zahlmann replies that these can be updated when needed, based on clinical and technical development.

Xavier Golay moves on to further clinical indications. Currently a metaanalysis on glioma, based on a systematic review, is included. From the metaanalysis it's possible to say something about sensitivity and specificity. Studies like this still need to be performed more, and are very interesting for clinical trials.

Xavier Golay shares that a round robin test of the phantom is scheduled for the end of October / November.

Furthermore, Xavier Golay wants to highlight the workshop organized by Luis Hernandez-Garcia in March 2019. The goal will be to look at current state of the white paper and determine if it needs to be revised.

Gudrun Zahlmann asks if the ASL committee wants to have a poster at this year's RSNA. Xavier Golay will summarize the current status of the profile. Gudrun Zahlmann adds that lessons-learned and describing the process is also valid as a contribution.

Xavier Golay thanks everyone for their attendance and closes the meeting.