QIBA Ultrasound Shear Wave Speed (SWS) Technical Committee

Monday, February 10, 2014; 1 PM CT Call Summary Notes provided by Dr. Garra

In attendance RSNA

Brian Garra, MD (Co-Chair)David Cosgrove, MDCedric Schmitt, PhDFiona MillerAndy Milkowski, MS (Co-Chair)Steven E. Fick, PhDMatthew Urban, PhDJoe KoudelikMichael Andre, PhDMike Macdonald, PhDMichael Wang, PhD, MAScJulie Lisiecki

Paul Carson, PhDStephen McAleavey, PhDKeith Wear, PhDJun Chen, PhDMark Palmeri, MD, PhDHua Xie, PhDShigao Chen, PhDAnthony Samir, MDJim Zagzebski, PhD

Moderator: Dr. Garra

Agenda:

- 1. Review of notes from prior meeting -
- 2. Subcommittee summaries and discussion
 - a. Phantoms and Systems Dependencies
- 3. Phantom material testing--Shigao Chen
- 4. Phantoms to create --- two soft, two hard, with viscosity similar to liver.

Study design discussion:

- a. Base on prior study?
- b. differences from prior study
- c. operators #
- d. depths
- e. number of data acquisitions per depth
- f. Roi sizes?
- g. Different horizontal locations in phantom or the same one or both?
- h. number of sites
- 5. Simulations and Phantom Simulation Status Mark Palmeri
- 6. Clinical
 - a. Status of analysis for clinical confounders
 - b. Status of Clinical Pilot Study
- 7. Other items to discuss
- 8. Adjourn
- Summary from January 10, 2014 Tech Ctte t-con was approved as written

Update on phantom materials testing

- Dr. Shigao Chen noted that his results using mechanical testing (shaking) were less viscous than those measured at the Duke Lab. He also noted that the range of viscosity values in the phantoms is somewhat less than the range of values seen in clinical patients. Ted Lynch will be updated with the results with a view towards modifying the phantoms.
 - The phantoms are available to anyone else who would like to test them
- Dr. Nightingale and her group intend to re-process the existing results to address some bias questions uncovered at Duke. A set of updated results from Duke will be presented at the next phantoms/system dependency meeting.
- Phantoms for the next round of testing were extensively discussed. Four new phantoms will be produced:
 - Two from FDA funding and two from QIBA funding, using two suppliers: CIRS and the University of Wisconsin, Madison.
 - o BG thought that one stiff phantom and one soft phantom each with viscosities similar to liver would be produced by each supplier. Others thought a different approach was needed.
 - O Andy Milkowski's proposal was to have phantoms with two different viscosities and two different stiffnesses BG noted that this would not allow for comparative testing of phantoms from CIRS vs. those from Wisconsin. Paul Carson proposed a compromise: two phantoms with middling viscosity and stiffness (one each from Wisconsin and CIRS) for comparison of the two phantom types plus one stiff phantom and one soft phantom. The question of what viscosity to use for the hard and soft phantoms. Paul asked if viscosity tracked with stiffness and Mark Palmeri said the data are too preliminary to be sure but that he thought it would be true in the end. So the soft phantom would have a lower different viscosity than the

- stiff phantom. A preliminary vote showed agreement with the compromise approach with Palmeri, Carson, Garra, Milkowski and Chen voting for it. Questions still remain and further discussion regarding this plan and the exact phantom properties will be needed.
- O Mark Palmeri thought that additional rounds of phantom material sample testing will be needed and this should be discussed at the next phantom meeting. Andy Milkowski asked if anyone had a good set of data showing the range of viscosity for abnormal and normal livers. No one was sure about the range and this will be further discussed to be sure of good agreement between phantoms and in vivo values.
- Discussion began regarding the study design
 - Question A: base the new design on the prior study? Andy Milkowski thought this was appropriate and Brian Garra agreed. No other comments.
 - O Question C: Number of operators. Consensus was to decrease the number of operators. Brian Garra suggested the possibility of a heterogeneous group of operators. Andy M. favored homogeneous trained set of operators to get the best results possible for analysis of machine variability and factors. Michael Andre felt that the operators should be experienced because they showed hardly a difference in results obtained in phase one. Andy M suggested one person per site who was familiar with the procedure collecting data that would be officially analyzed with other secondary operators collecting additional data runs for site specific analyses. Mark Palmeri suggested that the one operator selected for the new study should be selected from the group of operators from phase I. Shigao Chen agreed with this.
 - Question D: depths at which to acquire. Andy Milkowski suggesting using the same depths as before. It was clarified that "depth" referred to ROI depth, not focal depth. Paul Carson noted that at least one ROI should be at the focal depth. Initially Brian Garra summarized the discussion: ROI at three different depths plus one of which will be at the focal depth. On further discussion all agreed that the transducers used in the liver all had about the same focal depths so that one depth for the ROI at the focal depth could be used for all system reducing the number of depths to acquire to three total.
 - Question E: Number of acquisitions per depth. Andy Milkowski noted the 10 acquisitions per depth seemed to work well in phase I. It was noted that for a number of measurements, SSI deletes the upper and lower 10% to arrive at an estimate of mean from the remaining 80% of the measurements. Mike Andre, Brian Garra, and Hua Xie agreed that 10 total was appropriate.
 - Question G: Vary acquisition in physical location of phantom for each depth? Jim Zagzebski asked whether this happened in phase i. Mark Palmeri noted that only one location was used although the phantom could be rotated to get different planes of acquisition. It was tentatively decided to collect from one location to decrease variation and have one site vary locations to check on homogeneity of results from different locations in the phantoms.
 - Question F: ROI sizes. Anthony Samir noted that the clinical acquisitions were generally done at 10mm ROI size but that SSI could go to as small as 6mm. Andy Milkowski noted that the Siemens could only do 6mm on the abdominal transducer although on the linear the ROI size could be varied. Paul Carson noted that the ROI size should be standardized as much as possible. Hua Xie noted that the Philips ROI was fixed at 5 or 6mm is not changeable. Tentatively it was decided to use 6mm as the standard ROI size for phase II study.
 - Question H: Number of sites: Paul Carson suggested that neither sites nor observers should be added for
 phase II to be expanding the author list. Andy Milkowski thought that fewer sites should be considered
 since only one set of phantoms will be available. Further discussion will be needed on this issue. Dr.
 Palmeri stressed that the study design should have the same exact protocol configuration for
 reproducibility.
- Update on simulations of phantoms was deferred to the next meeting due to lack of time.

Clinical update

• Drs. Samir and Dhyani are on track with a review of the clinical literature for confounders with approximately 80 papers reviewed and about 25 patients recruited for the clinical study.

Other New Business

Paul Carson suggested that the committee begin discussion additional potential biomarkers and proposed the
possibility of volume blood flow. Brian Garra noted that volume flow was one of the final candidates for a
biomarker at the initial QIBA ultrasound meeting. The possibility of having Jonathan Rubin discuss this measure
was discussed. A version of the presentation made several years ago is on the QIBA wiki. See below.

Action Items:

Dr. Nightingale and team will share some test results on the next call.

- Garra, Hall and Milkowski to schedule further discussion of phantom compromise plan and of exact phantom properties needed for Phase II study. Also will schedule discussion of next phantom material samples to acquire.
- Dr. Jonathan Rubin to present an overview of Volume Flow Measurement on the next technical committee call (March 10th) for consideration as another possible Ultrasound biomarker effort.
- Dr. Rubin's slides are available on the QIBA wiki for review:
 http://qibawiki.rsna.org/images/1/10/QIBA Ultrasound Biomarkers Meeting%2C 03.29.2012-Dr. Rubin.pdf

Subcommittee Updates: Detailed project updates may be found on each subcommittee's page: QIBA wiki