



AIUM/QIBA Ultrasound Volume Blood Flow Biomarker

CALL SUMMARY 1-June-2020

Action Items in RED.

Attendance:

Stephen Pinter, Mark Lockhart, Brian Fowlkes, Oliver Kripfgans, Jonathan Rubin, Paul Carson, C-Y Lee, Rimon Tadross, James Jago, Cristel Baiu, Jing Gao, Michelle Robbin, Jim Zagzebski, Shriram Sethuraman

I. Previous Call Summary

Approved Review Summary from last call, with one request to add footnote regarding the first claim - flow is based on a phantom not human

II. Action Item

- One action left from the last meeting
 - Profile task force developed but need to send a Doodle poll to divide tasks.
 - BF will repurpose Doodle from CEUS BC
- Info on US CC
 - Dr. Carson added as co-chair
 - PEQUS now organizing with first call early June
 - Need to update Dashboard on google sheet - Chairs to update

III. Additional Discussion

- Update on Radiology Publication - Ground work is done
 - Oliver Kripfgans updated the BC
 - Radiology manuscript is accepted and will circulate within UMICH and then distribute with comments to the larger committee.
 - Radiology is offering coverage of work with Press Release

- Discussion at US CC - Shearwave manuscript was denied acceptance with Radiology because it did not include manufacture identification
 - Committee speculated that the differentiation is that VF is not commercially available, as opposed to SW.

Update on VBF Profile

- Reviewed calls from May
- Asked if anyone wants to join to let Therese know
 - Discussed accuracy of the phantom (see slide 7). Cristel agrees with statement of 0.5% and adds that his controlled bleed assessment was within 0.5 seconds of the high precision flow meter.
- Michelle Robbin will do a literature search - Maturation by ultrasound criteria
- Reviewed vessel size effects
- Reviewed 2D spectral Doppler measurement methodology
- For some systems, the default setup is max velocity (TAMXV), assuming a parabolic profile. This is a clear potential source of error in vivo. Typically used with intraabdominal rather than free looping cord.
- Automated diameter measurement - using Nuchal translucency
 - Semiautomated versus manual measurement discussed where one publication showed semiautomated had better performance.
- Intra-observer and Inter-observer 2016 study
 - 50 fetuses - two sets of measurements 30 minutes apart
 - 95% confidence interval was between 20% and 30%.

Action: Ask vendors what they use for the 2D spectral Doppler method for volumetric blood flow?

QIBA VBF Discussion

01-June-2020

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Review of Previous Call Summary

- Comments/Revisions
- Action Items

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Action Items from Previous Call Summary

- 3.1. Subsections need to be worked on
- 3.1.1. A doodle poll will be scheduled to strategize conquering sections
 - The VBF Profile Task Force has been meeting as a group for the first two calls to go over materials.
 - Doodle poll is still planned for the “division of labor”
 - Ideally, we will have leads for each section

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Information from Ultrasound Coordinating Committee Call

- *QIBA Process Committee*
- Dr. Carson has been added Co-Chair of US CC
- Backscatter (PEQUS) now organizing
- Dashboard Updates

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Update on Radiology Publication of Round Robin Groundwork

- Oliver...

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Update on VBF Profile Discussions

- Review of discussion for two calls in May
- Please join the task force
 - Doodle Poll to come

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Action Items from Previous VBF Profile Calls

- Discussed accuracy of phantom itself (Oliver K. to verify phantom specs., period over which data was collected.)
 - Oliver responded with the following.
 - Flow meter accuracy 0.5% of reading (+/- 0.25% based on measurements made by Cristel with a blood mimicking fluid (matched viscosity) and 2000 mL flask)
 - Data was collected 03/2017 to 03/2019
 - Additional information?
- Maturation by ultrasound criteria (Need to consult with Michelle R.)
 - Michelle responded with the following.
 - "The KDOQI criteria is as good a criteria as any. I am about to start updating the ACR guidelines for hemodialysis access so I'll review all the new literature in the next several weeks."

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Action Items from Previous Call Summary

- Discussed results of Rizzo et al. (J Matern Fetal Neonatal Med, 2016; 29(5): 701–706)
- Brian F. agreed to look at the measurement methods for such reproduction.

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Clinical Objective – Umbilical Flow

THE JOURNAL OF
MATERNAL-FETAL
& NEONATAL
MEDICINE

<http://informahealthcare.com/jmf>
ISSN: 1476-7058 (print), 1476-4954 (electronic)
J Matern Fetal Neonatal Med, 2016; 29(5): 701–706
© 2015 Informa UK Ltd. DOI: 10.3109/14767058.2015.1019853

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ORIGINAL ARTICLE

Modelling umbilical vein blood flow normograms at 14–40 weeks of gestation by quantile regression analysis

Giuseppe Rizzo¹, Ludovica Rizzo², Elisa Aiello¹, Eugenio Allegra¹, and Domenico Arduini¹

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Review of Rizzo et al 2016

- Study Population
 - 852 consecutive pregnancies referred for routine ultrasonographic assessment at 14–40 weeks of gestation.
- Inclusion Criteria
 - Singleton pregnancies
 - Successful recording of umbilical vein (UV) diameter and Doppler flow velocity waveforms
 - Accurate pregnancy dating by first trimester ultrasonography
 - Absence of pre-existing maternal diseases (diabetes, chronic hypertension, renal diseases)
 - Absence of fetal structural or chromosomal anomalies
 - Delivering >37 weeks of gestation
 - Normal maternal and neonatal outcome after exhaustive follow-up (i.e. delivery in our unit, thus allowing detection of eventual

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Review of Rizzo et al 2016

- Ultrasound Procedures
 - All examinations were performed by a single investigator (GR)
 - Voluson E8 or E6 (GE Medical Systems, Kretz Ultrasound, Zipf, Austria)
 - RAB4-8D abdominal transducers.
 - Doppler velocity waveforms and UV diameter were measured at the intra-abdominal straight portion of the vessel*

*UV diameter progressively decreases from the fetus to the placenta. (Li et al. J Biomed Mater Res B Appl Biomater 2006; 76: 93–97.)

What about cord perfusion?

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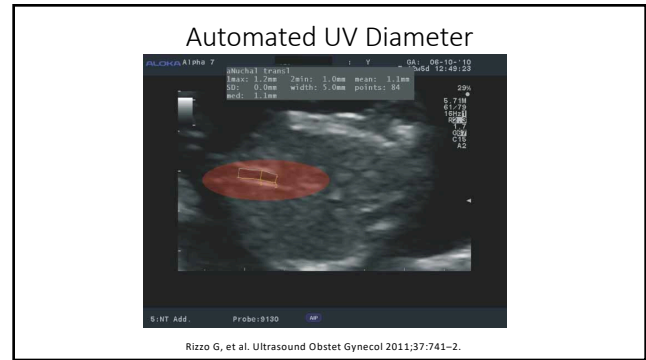
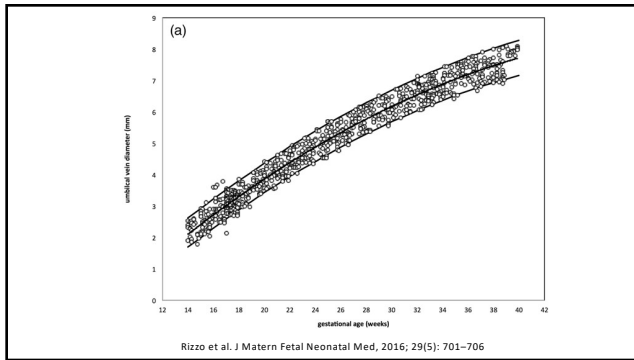
Review of Rizzo et al 2016

- Doppler Measurements
 - Doppler velocity waveforms were recorded for at least 10 s of uniform flow in periods of fetal quiescence
 - Angle of insonation as close as possible to 0 and always below 20 degrees
 - Time-averaged maximum velocity (TAMXV)
 - Maximum is biased.
 - UM Data for comparison for mean vs max.
 - Michelle Robbin presentation at AIUM – Jago
 - At next QIBA call ask vendors what they use?
- Diameter Measurements
 - UV was visualized perpendicularly
 - Internal diameter was measured using the automated function of the ultrasound equipment designed for nuchal translucency assessment†
 - The box for the measurement was placed on all the length of the UV and the inner-inner diameter obtained
- Volume Flow Calculation
 - $\pi \times (\text{UV diameter}/2)^2 \times 0.5 \times \text{TAMXV}$

"As in a cross-sectional study, only one recording was considered for each pregnancy."

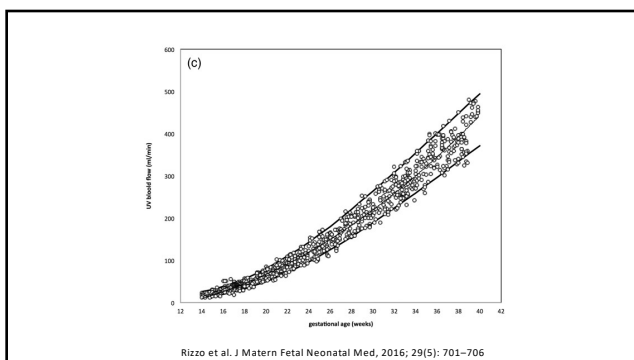
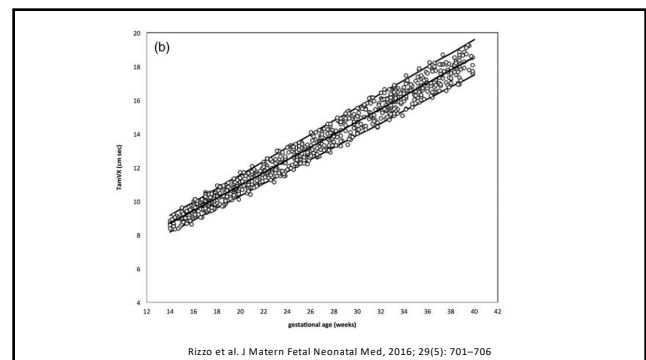
†Rizzo G, et al. Ultrasound Obstet Gynecol 2011;37:741–2.

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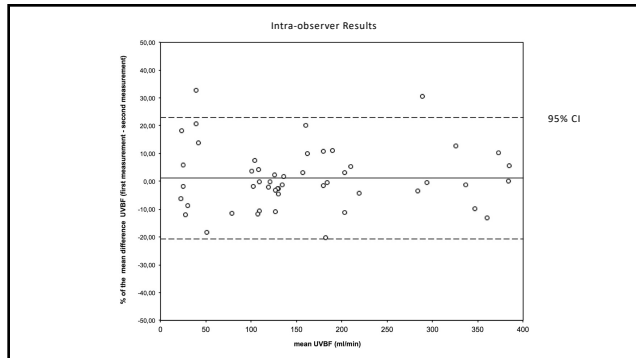
Automated UV Diameter

- Within-operator SD* values were significantly reduced with the semiautomated method
 - G.R.: manual, 0.111 (95% CI, 0.091–0.131) vs. semiautomated, 0.047 (95% CI, 0.036–0.059), $P < 0.0001$
 - A.C.: manual, 0.123 (95% CI, 0.091–0.154) vs. semiautomated, 0.049 (95% CI, 0.013–0.084), $P < 0.0001$.
- Interobserver reliability improved as well
 - Manual ICC = 0.883 vs. semiautomated ICC = 0.957



Review of Rizzo et al 2016

- Intra-observer study
 - Two sets of UV measurements were obtained in 50 fetuses at a time interval of approximately 30 minutes.
 - The ICC and their 95% confidence intervals: 0.92 (0.87–0.96)
 - In the Bland–Altman plot, the mean percentage difference and 95% limits of agreement were 1.01 (–21.87 to 23.85)

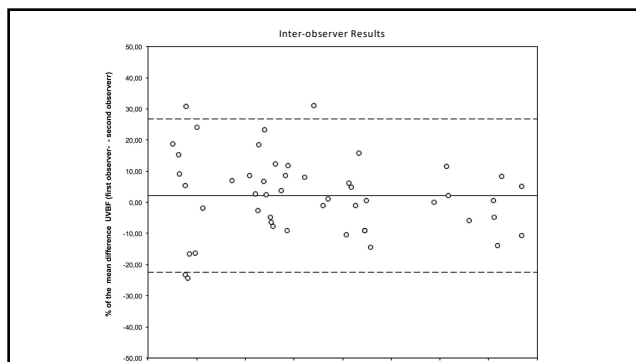


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Review of Rizzo et al 2016

- Inter-observer study
 - Different group of 50 fetuses.
 - Second observer blind to the measurements obtained by the first
 - UV measurements obtained at the end of the ultrasound session.
- The ICC and their 95% confidence intervals: 0.89 (0.84–0.97)
- In the Bland–Altman plot, the mean percentage difference and 95% limits of agreement were 1.12 (–20.70 to 22.95)

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Matters Arising

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