Achievements, Challenges, and Present Status of QIBA’s Ultrasound Volume Blood Flow Committee

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Disclosures

Histosonics – One of the Founders and Scientific Advisors with financial interest.

Philips Healthcare – Research collaborations

GE Healthcare – Research collaborations

QIBA Committee Leadership

• Co-chairs
  – J. Brian Fowlkes, PhD
  – Oliver D. Kripfgans, PhD
  – James Jago, PhD

Participating Institutions (Alphabetical)
Participating Companies (Alphabetical)

- Aloka Medical America
- CIRS
- Gammex - Sun Nuclear
- GE Healthcare
- Hitachi
- Pfizer Inc.
- Philips Healthcare
- Siemens Healthcare
- Canon Medical Systems

Doppler Equation

\[ f_D = 2f \cos \theta \frac{v_o}{c} \]

- \( f \) = center frequency of transmitted ultrasound
- \( \theta \) = Angle of motion with respect to sound propagation
- \( v_o \) = velocity of blood
- \( c \) = sound speed

Flow Indices and Metrics

- Variety of flow indices used for assessing flow.
  - Less operator dependence than absolute flow measures
- S/D ratio = (systolic / diastolic ratio)
- Resistance index (RI) = ([systolic velocity - diastolic velocity] / systolic velocity)
- Pulsatility index (PI) = ([systolic velocity - diastolic velocity] / mean velocity)

Tortuous Umbilical Cord Flow

Flow Indices vs. Flow Velocity

- Same flow velocity but VERY DIFFERENT VOLUME FLOW!!!!!
Volume Flow (Q) vs. Flow Velocity (V)

\[ Q = \int V \cdot dA \]

Same flow velocity but VERY DIFFERENT VOLUME FLOW!!!!!

Traditional Doppler Volume Flow

- Required for Measurement
  - Doppler Angle
  - Diameter
  - Circular Cross Section
  - Axial Symmetry


Umbilical Cord Flow

Doppler Angle? Circular Cross Section?


Umbilical Cord Flow

Axial Symmetry?


So what do we do about this?

Alternative method for estimating blood flow (mL/min) using 3D/4D Doppler ultrasound

Eliminate the limitations of pulsed-wave Doppler
- Doppler Angle
- Vessel Diameter/Circularity
- Flow Symmetry

Proposed 3D/4D method overcomes limitations
3D/4D Volume Flow
Integration of Color Flow Velocity Vector Function Normal to the C-plane Surface Yields Blood Volume Flow

\[ Q = \oint_S \mathbf{V} \cdot d\mathbf{A} \]

Clinical Umbilical Flow Study

Summing over Weighted Pixels
C-surface Image

\[ Q = \sum v_i (A_i \times w_i) \]

Doppler Power Histogram

Mechanically Swept Probes
GE Healthcare

Fully Electronic (2D array) Probes
Philips xMatrix
GE Voluson e4D
Clinical Umbilical Flow Study

- 35 patients each with a singleton pregnancy
  - Recruited from a population at an increased risk of preeclampsia.

- Classified into 3 groups:
  - 21 at-risk patients
  - 5 with preeclampsia (29.7-34.3 weeks GA)
  - 9 with normal pregnancies (25.9-34.7 weeks GA)


Images acquired on a LOGIQ E9 with a 2.0–8.0-MHz bandwidth array transducer (RAB6-D)

- Three different free loop positions along the length of the cord:
  - Intra-subject and intra-measurement relative standard error (RSE) were 12.1 ± 5.9 and 5.6 ± 1.9 % (mean ± SD), respectively.


Clinical Umbilical Flow Studies

Quantitative Imaging Biomarker Alliance (QIBA)

- QIBA Mission: Improve the value and practicality of quantitative imaging biomarkers by reducing variability across devices, sites, patients, and time.

Complex Flow Phantom

Calibrated Volumetric Flow

QIBA Phantom
Ultrasound Systems in this Study*  
- Canon (formerly Toshiba) Aplio 500 with a mechanically swept 9CV2 probe  
- GE Logiq LE9 with a mechanically swept RSP6-16 probe  
- Philips Epiq 7 with an X6-1 2D matrix array  

* Other participating companies have systems in development.

Scope of Study

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<th>Dataset size</th>
<th>No. volumes scanned</th>
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<tbody>
<tr>
<td>No. systems</td>
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</tr>
<tr>
<td>No. sites</td>
<td>3</td>
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<td>No. flow modes</td>
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<td>No. parameter steps per test</td>
<td>(flow) 11 (depth) 17 (gain) 6 (transmit)</td>
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<tr>
<td>No. parameter steps per test</td>
<td>(pulsatile) 12 (flow) 11 (depth) 12 (gain) 6 (transmit)</td>
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<tr>
<td>Total no. datasets</td>
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<tr>
<td>Total no. volumes</td>
<td>18,450</td>
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</table>

Flow Range Dependence

Depth Range Dependence

Effect of Stenosis

Constant vs. Stenotic Flow
Summary of Phantom Results

- Volume flow estimated by 3D color flow ultrasound was:
  - Accurate (11.5% mean bias)
  - Reproducible (10.4% mean within-subject CV)
- There were differences among systems that are still being examined.
- There are changes being made to systems expecting to improve performance.
- Phantom accuracy:
  - Data collected over several months (03/2017 to 03/2019).
  - Phantom was not recalibrated during this period.
  - Two phantoms were circulated.
  - Flow meter accuracy 0.5% of reading (+/- 0.25% based on measurements made with a blood-mimicking fluid (matched viscosity) and 2000 mL flask)

Rubin et al. Umbilical Venous Study Results

- The true flow was unknown for these case (no reference standard)
- Mean within-subject coefficient of variation (wCV)
  - Spectral Doppler method: 46 ± 17%
  - 3D/4D Gaussian surface method: 18 ± 14%

Clinical Objective – Umbilical Flow

- Intra-observer study:
  - Two sets of UV measurements were obtained in 50 fetuses at a time interval of approximately 30 minutes.
- 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.
Potential Associated Claims

1. **Claim 1**: (cross-sectional) For a measured volume blood flow of $X$ mL/min, a 95% confidence interval for the true flow is $X$ mL/min ± 15%.

2. **Claim 2**: (technical performance claim) The volume flow measurement has a within-subject coefficient of variation (wCV) < 20%.

Thanks!

$$Q = \int \vec{v} \cdot d\vec{A}$$