Intra-Procedural Real-Time Flow Monitoring

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Disclosure

Speaker name: Mahmood Razavi MD

I have the following potential conflicts of interest to report:

- **Consulting:** Abbott, BSC, LAS, MDT, Philips, Terumo
  - x
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Research support: BD, BSC, Mercator, Philips, NIH
  - x

I do not have any potential conflict of interest
Background

• Ankle Brachial Index (ABI) is a common non-invasive, first line diagnostic tool used to evaluate presence of PAD\(^1\)

• ABI is an inaccurate measure of disease burden in many situations such as calcified vessels or those with small vessel disease \(^2\)

• Currently, Toe Brachial Index (TBI) is the gold standard for noninvasive assessment of PAD severity in the critical limb ischemia (CLI) population\(^1\)

• Novel technologies for perfusion/flow monitoring may present advantages over traditional technologies

Typical Intra-procedural Issues

- How many lesions or vessels need to be treated?
- Have I done enough?
- Should I stent the recoil or the dissection?
- Did I establish enough flow?
- Should I treat some of the lesions and bring the patient back if the symptoms are not resolved?
Typical CLI case
Should the dissection be stented?
Technology

FlowMet System

• Utilizes laser speckle imaging technique to quantify blood flow/perfusion
• Measures average volumetric flow within the digit
• Displays **flow values** and **waveform** in real time
• System intended for intraprocedural monitoring
FlowMet Output Example*

*Data on file at LAS
Flow Waveform Changes with PAD Severity

- Proprietary FlowMet Index (FMI) uses flow and waveform information to predict PAD severity

*Data on file at LAS*
FlowMet Index (FMI)

Blood Flow
- Average blood flow value

Waveform Shape
- Phasicity
- Slope
- Width

FMI = 0.85
Study Overview

• Determine the correlation of FlowMet with standard noninvasive diagnostic assessments

GOAL

PATIENT POPULATION

• Cross sectional study
  167 limbs in 100 patients
• All comers scheduled for arterial exam at an outpatient vascular clinic

Study Protocol

1. Informed consent (n=100)
2. ABI, TBI, and Rutherford class assessment (n=100)
3. 30 second FlowMet assessment of perfusion (n=100)
<table>
<thead>
<tr>
<th>TBI Value</th>
<th>Toe Pressure [mm Hg (mean +/- SD)]</th>
<th>FlowMet Peak Flow [a.u. (mean +/-SD)]</th>
<th>Waveform (phasicity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 0.5</td>
<td>99.7 +/- 22.5</td>
<td>8.3 +/- 3.9</td>
<td>Biphasic / Triphasic</td>
</tr>
<tr>
<td>0.2 – 0.5</td>
<td>55.3 +/- 15.9</td>
<td>6.5 +/- 3.8</td>
<td>Monophasic / Biphasic</td>
</tr>
<tr>
<td>&lt; 0.2</td>
<td>16.8 +/- 9.7</td>
<td>3.5 +/- 2.6</td>
<td>No waveform / Monophasic</td>
</tr>
</tbody>
</table>
Results: ABI and TBI Correlation to FlowMet Index

FlowMet Index (FMI) Correlation to ABI and TBI

- ABI: \( r = 0.59 \), \( p < 0.001 \)
- TBI: \( r = 0.55 \), \( p < 0.001 \)
FlowMet Study Results: Rutherford Correlation

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Correlation to RCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI</td>
<td>$r = -0.41$, $p &lt; 0.001$</td>
</tr>
<tr>
<td>TBI</td>
<td>$r = -0.60$, $p &lt; 0.001$</td>
</tr>
<tr>
<td>FMI</td>
<td>$r = -0.63$, $p &lt; 0.001$</td>
</tr>
</tbody>
</table>

![Box plots showing the correlation between FlowMet Index (FMI) and Rutherford Class]

(a)
FlowMet Index as a CLI Diagnostic Measurement

- Receiver operating characteristics (ROC) curve was generated for predicting CLI*
- FlowMet Index (FMI) demonstrated improved area under the curve (AUC) compared to TBI & ABI

*Defined as Rutherford class ≥ 4 confirmed with Duplex
Based on FMI, this pt did not need a stent
Baseline

Balloon inflated in anterior tibial

Balloon deflated in anterior tibial

Blood Flow [a.u.]

Time Since Start [s]

Catheter removed

Image 87
Baseline

Balloon inflated in anterior tibial

Balloon deflated in anterior tibial

Catheter temporarily removed

Balloon inflated in anterior tibial

Balloon deflated in anterior tibial

Balloon inflated in peroneal

Catheter removed, procedure complete

Blood Flow [a.u.]

Time Since Start [s]

Baseline

Balloon inflated in anterior tibial

Balloon deflated in anterior tibial

Catheter temporarily removed

Balloon inflated in anterior tibial

Balloon deflated in anterior tibial

Balloon inflated in peroneal

Catheter removed, procedure complete
Follow up Application

Intra-procedural pre & post flow & waveforms in an 81 YO female with distal plantar 1\textsuperscript{st} MTP NHW & 3-vessel CTO
Tracings 24hrs post revascularization
• FlowMet Index (FMI) demonstrated a higher correlation to TBI than ABI
• FMI demonstrated a higher correlation to Rutherford Classification than ABI or TBI
• FMI is diagnostically relevant with sensitivity and specificity curves similar to TBI utilizing only a simple toe clip
• Real time output of the FlowMet system may be beneficial for intraprocedural monitoring without impeding procedural flow
Intra-Procedural Real-Time Flow Monitoring

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