Validity of neonatal POC glucose testing

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Validity of neonatal POC glucose testing

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Background
Glucose monitoring a common invasive intervention in newborn period
• most commonly obtained laboratory value
Appropriate identification of hypoglycemia is critical:
• Severe hypoglycemia can lead to neurologic insult
• Cerebral palsy, developmental delay, seizures, death

Critical Issues
POC glucometers are subject to error in situations very common in neonates:
- Hypoxemia
- Poor perfusion
- Hyperbilirubinemia
- Abnormal hematocrit
- Acetaminophen administration
- Alcohol on the overlying skin
- Peripheral vasocostriction

Current Recommendations vary:
ISO 2003 - 95% of values should fall:
• within +/- 15 mg/dl for glucose concentrations < 75 mg/dl
ISO 2013 - 95% of values should fall:
• within +/- 15 mg/dl for glucose concentrations < 100 mg/dl
FDA 2014 - 99% of all values should fall:
• within +/- 7 mg/dl for values < 70 mg/dl

Analysis of 17 different POC devices in 2017:
- 7 met ISO 2003 Criteria.
MMC uses FreeStyle Precision Pro meters, manufactured by Abbott
• No independent validation trial
• Manufacturer website states that they are ISO 2013 compliant
• Not studied in neonates

Study
What is the accuracy of neonatal glucose measures at MMC?

Methods
• Retrospective data analysis
INCLUDED:
• all infants on the FM and Newborn services from July 1st, 2017 to June 30th, 2018.
• < 30 days old
• had both a POC and a serum measurement performed within 30 minutes of one another, and no documented feeding or administration of glucose in the intervening time
EXCLUDED:
• Infants w/glucose of nutrition within 30 min of

Characteristics of Patients

<table>
<thead>
<tr>
<th>Delivery Type</th>
<th>Number of infants</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal</td>
<td>74</td>
<td>52.48%</td>
</tr>
<tr>
<td>C-section</td>
<td>65</td>
<td>46.10%</td>
</tr>
<tr>
<td>Transfer from outside hospital</td>
<td>2</td>
<td>1.42%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age in days</th>
<th>Number of infants</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>66</td>
<td>46.81%</td>
</tr>
<tr>
<td>1</td>
<td>52</td>
<td>36.88%</td>
</tr>
<tr>
<td>2-3</td>
<td>19</td>
<td>13.48%</td>
</tr>
<tr>
<td>4+</td>
<td>4</td>
<td>2.84%</td>
</tr>
</tbody>
</table>

| SGA          | 19                | 13.48%  |
| LGA          | 18                | 12.77%  |
| At risk of hypoglycemia | 42       | 29.79%  |
| DM in Mother | 10                | 7.09%   |
| Neonatal sepsis | 0           | 0.0%    |
| Hypoglycemia  | 19                | 13.48%  |
| Neonatal seizure | 0           | 0.0%    |
| Neonatal asphyxiation | 4        | 2.84%   |
| Infants with multiple diagnoses | 19      | 13.48%  |

RESULTS

<table>
<thead>
<tr>
<th>Number of samples</th>
<th>Number of POC mg/dl different than Serum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>141</td>
</tr>
<tr>
<td>Serum &lt;40</td>
<td>31</td>
</tr>
<tr>
<td>Serum &gt;40</td>
<td>110</td>
</tr>
</tbody>
</table>

| Mean Serum - POC reflects degree of bias. All categories have significant error in measurement, but only in neonates with low serum measurements is that error biased toward overestimation. |

CONCLUSIONS:
• Our meter appears to have poor sensitivity for hypoglycemia
• Our meter appears to have clinically significant error, with a bias toward overestimation of glucose in hypoglycemic infants
• Our meter does not appear to be meeting FDA or ISO guidelines in this population

Strengths and Limitations

Acknowledgements
Thank you to David Cox, MD; Brian Youih, MD; Timothy Hayes, MD, DVM for their assistance and support.

Related Literature


Our meter does not appear to be meeting FDA or ISO guidelines in this population