Validity of neonatal POC glucose testing

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Validity of neonatal POC glucose testing

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Background

Glucose monitoring is 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:
• Hypo/hyperglycemia
• 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 < 100 mg/dl
ISO 2013 - 95% of values should fall:
• within +/- 5 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.
• 2 met ISO 2013 criteria (Ekhlaspour et al, 2017).

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

RESULTS

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 the first measurement with rising glucose value

Characteristics of Patients

Table 1: Properties of blood glucose samples by delivery type, age, and ICD10 codes (N=141)

<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>

Age in days

<table>
<thead>
<tr>
<th></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

<table>
<thead>
<tr>
<th></th>
<th>Number of infants</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>equal</td>
<td>19</td>
<td>13.48%</td>
</tr>
<tr>
<td>LGAs</td>
<td>18</td>
<td>12.77%</td>
</tr>
</tbody>
</table>

At risk for hypoglycemia

<table>
<thead>
<tr>
<th></th>
<th>Number of infants</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>equal</td>
<td>42</td>
<td>29.79%</td>
</tr>
<tr>
<td>GM in Mother</td>
<td>10</td>
<td>7.09%</td>
</tr>
</tbody>
</table>

POC Glucometer performance relative to ISO Guidelines

Table 2: Comparison of POC and serum glucose values

<table>
<thead>
<tr>
<th>Serum</th>
<th>Number of samples</th>
<th>Mean POC</th>
<th>Mean Serum</th>
<th>Mean Serum - POC</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;40</td>
<td>31</td>
<td>33.67</td>
<td>32.90</td>
<td>-0.77</td>
</tr>
<tr>
<td>≥40</td>
<td>110</td>
<td>10.42</td>
<td>10.46</td>
<td>0.04</td>
</tr>
</tbody>
</table>

POC Sensitivity for BG <40: 64.5% (± 16.4%) POCSensitivity for BG >40: 52.6% (± 15.9%)

CONCLUSIONS:
• Our POC 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

Retrospective data analysis resulted variable timing of POC and serum testing (mean of 16 minutes between samples, SD of 8 min). This study would benefit from an interventional design with simultaneous measurements.

All intervention times were based on Epic records, which may not be entirely accurate or complete.

Acknowledgements

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Related Literature


