Simultaneous Device Wear May Disclose Disparate Continuous Glucose Monitoring Performance

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Introduction
Various approaches have been considered to measure the accuracy and utility of continuous glucose monitors, and to compare results between monitors. Because of the dynamic nature of diseases such as diabetes, many evaluation methods, such as the original Clarke error grid, Pearson correlation, and area under the curve (AUC) have been criticized as being inaccurate or inappropriate tools.1, 2

We designed a more direct and practical method for comparing continuous monitor results, and for determining an appropriate device for individual users within the clinical setting.

Today's continuous monitors are different from prior CGMS systems in that:
A) current estimated blood glucose values are openly displayed to users.
B) adjustable alerts are available to warn users when their glucose crosses a low or high threshold.

With an open display, the accuracy and timeliness of displayed readings and warnings become quite important. If users overly trust the monitor's readings, they may make inappropriate clinical decisions. Neither of these monitors is approved for clinical use independent of a meter test. In comparing sensors, the most important decision for many users is whether the sensor will accurately warn of hypoglycemia and continuous monitors have had difficulty doing this.3

Fortunately, when two different sensors are worn at the same time, the sensors can be set with identical high and low alerts to determine which one provides the most appropriate information. This study utilized the internal warning system of the monitors, combined with frequent daily fingerstick tests and additional fingertip stick tests done when a disagreement occurred between two displayed readings to test the appropriateness of warnings and the accuracy of displayed readings.

Methods
One individual (59 yo male with IDDM and recent A1c of 6.4% on an insulin pump) volunteered to wear two CGM devices from different manufacturers and to compare their displayed results with simultaneous readings from a One Touch Ultra meter. The readings generally reflect real life circumstances, although hypoglycemia and hyperglycemia were at times voluntarily induced to further test the accuracy and responsiveness of the sensors.

The low alert was set to 80 mg/dl and high alert to 160 mg/dl in each monitor. When an alert was sounded by one of the sensors, readings from both sensors were recorded and a fingertip test with an Ultra meter was obtained. Routine testing was also done with results from both sensors recorded at those times. When a significant difference in values was noted between the sensors, such as greater than 30 mg/dl, an additional fingerstick test was done. Each sensor was operated as directed. Each required calibration tests per day and those calibrations rarely occurred at the same time. Calibration was performed from the same Ultra meter. On some days, 1 to no more than 2 additional calibrations were done for both sensors simultaneously, averaging about 1 extra calibration per day per sensor.

How Different From The Ultra Was Each Sensor?

<table>
<thead>
<tr>
<th>Difference in BG:</th>
<th>Sensor A</th>
<th>Sensor B</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-9 mg/dl</td>
<td>54</td>
<td>21</td>
</tr>
<tr>
<td>10-19 mg/dl</td>
<td>42</td>
<td>28</td>
</tr>
<tr>
<td>20-29 mg/dl</td>
<td>15</td>
<td>23</td>
</tr>
<tr>
<td>30-39 mg/dl</td>
<td>9</td>
<td>19</td>
</tr>
<tr>
<td>40-49 mg/dl</td>
<td>3</td>
<td>17</td>
</tr>
<tr>
<td>50-59 mg/dl</td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>60-129 mg/dl</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>129 readings for each sensor</td>
<td>8</td>
<td></td>
</tr>
</tbody>
</table>

When sensors differed in value, only rarely was this due to a delay in response. On occasion, Sensor B would ultimately catch up to the full drop or rise displayed by Sensor A, usually 15 to 60 minutes later. More often, however, Sensor B never achieved the full drop or rise. This can be noted by the difference in SD and by the results in the paragraph above.

Mean average deviation:
Sensor A: 15.9%
Sensor B: 31.4%

Conclusions
1. Continuous monitors may differ in performance in a single individual.
2. Failure or delay in recognition of hypoglycemic or hyperglycemic trends may be clinically significant.
3. Side-by-side performance evaluations of monitoring devices may be important to understand the potential for missed or delayed recognition of out-of-range glucose values.
4. Further studies are required to determine the characteristics that will predict which CGMS device will provide optimum outcomes in an individual patient.

References
3. Endocrine Practice: Volume 10, Number 4 July / August 2004, pgs 324-329

Comparison of Ultra and Sensor A

Comparison of Ultra and Sensor B

R = 0.93

R = 0.74