Evaluation of the Nova Biomedical Statstrip glucose meter

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Abstract

Aims: The Nova StatStrip blood glucose monitoring system was evaluated for precision, accuracy, and interferences from haematocrit and maltose. It was also compared against three other meters and two reference methods.

Methods: Heparinised whole blood samples were analysed on the meters. These results were compared with whole blood samples analysed on the Radiometer ABL835 for the interference studies. Plasma samples, obtained from these whole blood samples, were measured on the Abbott Ci8200 for accuracy studies.

Results: There were significant differences in the degree to which the meters correlated with the reference method. With the exception of the StatStrip, all meters were affected by variable haematocrit. Of the two glucose meters tested, the StatStrip did not show any maltose interference.

Conclusions: The StatStrip glucose meter did not show clinically significant interference from maltose or varying haematocrit levels. In addition, the StatStrip demonstrated the best correlation with the glucose reference method.

Key words: glucose, point-of-care, interferences, precision, bias

Introduction

Point-of-care glucose meters are increasingly being used to make therapeutically important decisions. At Middlemore Hospital we are currently using approximately 160 glucose meters in the diabetes clinic, ICU, neonatal unit and other wards. It is essential that the results from these meters can be relied upon for clinical decisions, and therefore that they correlate well with those of the laboratory analysers.

A major concern of the use of point-of-care glucose meters is analytical interference. Patients are frequently taking numerous medications and critically ill patients and neonates often have an abnormal haematocrit. Previous studies have shown that both maltose(1-3) and haematocrit (3,4) have compromised performance of glucose meters.

Recently, companies have introduced improved glucose meters which are less affected by these interferences. The aim of this study was to assess the performance of the Nova Biomedical Statstrip blood glucose monitoring system evaluated for precision, accuracy, and interferences from haematocrit and maltose. It was also compared against three other meters and two reference methods.

Methods

Glucose meters tested

Nova Biomedical StatStrip, Arkray Glucocard, Roche Accu-Chek Advantage, Abbott Precision PCx Plus and the reference method was Radiometer ABL835 (reference method was chosen to obtain haematocrit and glucose)

Interference study

Fresh heparinised venous blood drawn from healthy donors was used and allowed to sit at room temperature for 24 hours so that the glucose was almost completely depleted before concentrated solutions of glucose and interfering substances were added. Immediately prior to each interference study, the two blood tubes were spiked with a 1.1mmol/L glucose solution to obtain a low and high glucose range and mixed for at least 10 minutes by rocking.

Haematocrit interference

Each of these two blood tubes was further divided into 4 aliquots of 1ml. Centrifugation, using a micro-centrifuge, and plasma adjustments resulted in three aliquots with different haematocrit levels (22%, 45% and 62%) for each concentration of glucose. All six aliquots were rocked at least 10 minutes before analysis.

For each glucose meter there were 5 replicate measurements at 3 haematocrit levels and 2 different glucose levels, giving a total of 30 data points per meter. The haematocrit interference graph was generated for each tested glucose level using the average recovered value of the 5 replicates obtained for each interference level on each manufacturer's meter.

For each glucose meter there were 5 replicate measurements at each of 3 maltose levels and 2 different glucose levels, giving a total of 30 data points per meter. The maltose interference graph was generated for each tested glucose level using the average recovered value of the 5 replicates obtained for each investigated interference level on each manufacturer's meter.

For each glucose meter there were 5 replicate measurements at each of 3 maltose levels and 2 different glucose levels, giving a total of 30 data points per meter. The maltose interference graph was generated for each tested glucose level using the average recovered value of the 5 replicates obtained for each investigated interference level on each manufacturer's meter.

Correlation and bias

This was performed by analysing 120 heparinised whole blood specimens on the four glucose meters, compared to plasma obtained from those specimens and analysed on the Ci8200 as reference method. The range of glucose values was 2.3-20.2 mmol/L.

The precision study on the StatStrip was performed by analysing five random heparinised whole blood samples at 20 replicates with a glucose range of 1.0-34.0 mmol/L.

Correlation was by least square linear regression and bias by Altman-Bland plots.

Results

With the exception of the StatStrip, all meters were affected by variable haematocrit (Figures 1 and 2). There was a clear trend for negative bias associated with increasing haematocrit for the PCx, Advantage and Glucocard. Of the two glucose meters tested for maltose interference the StatStrip did not show any significant changes (Figures 3 and 4).

There were significant differences in the degree to which the meters correlated with the reference method. The StatStrip, with a R² of 0.226 was the one which correlated best with the hexokinase plasma reference method, followed by the Advantage with a R² of 1.092, while the Glucocard with a R² of 2.998 and the PCx with a R² of 4.213 correlated badly with the reference method (Figures 5-8).

All four meters demonstrated a negative bias. The StatStrip, with a bias from -0.476, was the lowest, followed by the Advantage with a bias of -0.747, PCx with a bias of -1.045 and Glucocard with a bias of -1.731 (Figures 5-8).
Precision was assessed for a glucose range between 1.0 and 33.0 mmol/L. The StatStrip showed coefficients of variation (CV) of less than 6% with the exception of a critical low glucose level (<1 mmol/L), where it was more than 13% (Table 1).

**Table 1.** Within run precision of the Statstrip (n=20)

<table>
<thead>
<tr>
<th>Glucose</th>
<th>CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.7-1.3 mmol/L</td>
<td>13.4 %</td>
</tr>
<tr>
<td>1.1-1.6 mmol/L</td>
<td>4.8 %</td>
</tr>
<tr>
<td>1.9-2.4 mmol/L</td>
<td>5.1 %</td>
</tr>
<tr>
<td>6.3-6.5 mmol/L</td>
<td>1.9 %</td>
</tr>
<tr>
<td>30.1-33.7 mmol/L</td>
<td>2.5 %</td>
</tr>
</tbody>
</table>

**Discussion**

This study has shown that precision for the StatStrip glucose meter was acceptable as well as the correlation study. The StatStrip and the Advantage demonstrated the closest correlation with the plasma hexokinase reference method and demonstrated the lowest absolute bias. The glucose meter that is currently in use at Middlemore hospital, the Glucocard glucose meter demonstrated the second worst correlation with the reference method from the four glucose meters tested. We found similar results for haematocrit and maltose effect on glucose meter that have been published previously.(1-5).

In conclusion, the StatStrip glucose meter did not show clinically significant interference from maltose or varying haematocrit levels. In addition, it demonstrated the best correlation with the reference glucose method.

**Acknowledgements**

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**References**

Figure 5. Correlation and bias of Statsstrip versus reference (CI 8200)

Figure 6. Correlation and bias of Glucocard versus reference (CI 8200)

Figure 7. Correlation and bias of PCx versus reference (CI 8200)
Figure 8. Correlation and bias of Advantage versus reference (CI 8200)