PERFORMANCE OF THE STATSTRIP GLUCOSE METER IN INPATIENT MANAGEMENT OF DIABETES MELLITUS

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SUMMARY

The use of hospital point-of-care glucose meters in inpatient care is widely established despite unsolved issues regarding accuracy. The aim of this study was to validate the performance of the StatStrip Glucose Hospital Meter (Nova Biomedical, Waltham, USA) in performing glycemic profile in hospitalized diabetic patients undergoing intensified insulin therapy. We investigated total imprecision, inaccuracy, and analytical range limits by measuring glucose in 481 plasma samples of diabetic patients. Total imprecision was 2.4% and linearity ranged from 1.3 to 31.9 mmol/L. The results correlated well ($r=0.9868$) with the laboratory routine procedure with a determined bias of 2.1%. Total error of the method was 4.5%, which was within designated criteria for laboratory glucose measurement. Diagnostic testing revealed a 100% sensitivity and 100% specificity in detection of hypoglycemic episodes ($n=16$), respectively. StatStrip Glucose Hospital Meter is a simple, accurate and reliable tool for assessing glycemia levels in inpatient management of diabetes mellitus.

INTRODUCTION

Diabetes is a chronic disorder requiring complex and continuous medical care (1). The World Health Organization has reported on a dramatic increase in its prevalence with a global estimate of 366 million people with diabetes by 2030 (2). Clinical evidence has clearly indicated that improved metabolic control leads to a significant reduction in microvascular complications associated with diabetes. Apart from achieving optimal glycemic control it is of great importance to avoid short-term fluctuations, i.e. periods of hyper- and especially hypoglycemia (1). Optimal everyday tuning of intensified insulin therapy requires establishment of glycemic profile by frequent blood glucose measurement (premeal, 90 min postmeal, prebed and at 3:00 A.M.), which is performed by patients, using self-monitoring blood glucose instruments (3). However, intensified insulin treatment at initiation and/or modification must be rigorously evaluated by accurate measurement of glycemic profile under controlled conditions during short-term inpatient management.
The use of hospital point-of-care glucose meters in these procedures is widely established, despite controversies regarding insufficient precision and inaccuracy of measurement due to various interferences (4). Point-of-care testing (POCT) is analytical testing performed outside central laboratory using a device or devices that can be easily transported to the vicinity of the patient. The main advantages of POCT are decreased amount of blood needed for testing and decreased total turnaround time (TAT). It is essential that its use can be managed appropriately and safely for both patients and staff (5). The variability of results between POCT glucose meters and central laboratory is partly due to the user-related errors, which can be overcome by intensified education and appropriate quality control (6). However, preanalytical patient-related variables (physiology, hemodynamics, drug treatment) and analytical performance of glucose meter are both factors of great importance when considering appropriate use of point-of-care technology for inpatient glucose measurement (7). Despite major advances in technology, most point-of-care glucose meters are still not up to rigorous criteria for accurate glucose measurement with a total allowable error set to 10% (8).

One of the new generation hospital point-of-care glucose meters is StatStrip Glucose Meter (Nova Biomedical, Waltham, USA), with a turnaround time of 6 seconds and the amount of blood of 1.2 µL per measurement. Its unique advantage is no interference from hematocrit, which can be substantially reduced in diabetic patients with kidney damage, and changed both ways in critically ill patients (9). Hemoconcentration and hemodilution are associated with falsely decreased and elevated glucose measurements, respectively, mostly due to changes in physical interactions of plasma with the strip reagent layer (7). StatStrip Glucose Meter technology provides actual measurement and correction for hematocrit together with glucose measurement on the same strip, resulting in significant reduction of hematocrit-related errors (10).

The aim of this study was to validate the performance of StatStrip Glucose Hospital Meter in performing 8-point glycemic profile in hospitalized diabetic patients treated with intensified insulin therapy.

MATERIALS AND METHODS

Instrumentation

The comparison method was routine laboratory glucose-oxidase chromogenic method on an AU400 routine laboratory analyzer (Beckman Coulter, Tokyo, Japan) (11). Tested glucose meter was StatStrip Glucose Hospital Meter (Nova Biomedical, Waltham, USA), which uses a modified glucose oxidase-based amperometric test system with unique hematocrit correction via actual measurement on the same strip. Test system is equipped with a chemical/drug-interference blanking system and a sampling control on the test strip. Results are expressed in plasma-glucose equivalents, according to current recommendations (1,12).

Blood sampling procedure

Blood samples were obtained from type 1 diabetic patients treated with intensified insulin therapy, during routine inpatient management.

Routine laboratory procedure: capillary blood (50 µL) was withdrawn with a calibrated pipette and immediately transferred to 1 mL of diluting reagent (100 mg NaF + 50 mg EDTA in 1000 mL saline). Diluted blood samples were centrifuged (10 min, 1200 g) and glucose was determined in diluted plasma supernatant. Total amount of capillary blood necessary for 8-point glycemic profile is 400 µL.

StatStrip Glucose Hospital Meter: blood sample was aspirated by the capillary system to the test strip from freely formed drop of blood, after a sample for the routine procedure was withdrawn from the same fingerprick. The amount of blood needed for one test is 1.2 µL and the total amount of capillary blood necessary for 8-point glycemic profile is 9.6 µL.
Precision studies

Within-run imprecision. Three venous EDTA whole blood samples with clinically relevant concentrations of glucose were tested 20 times on StatStrip Glucose Hospital Meter. The criterion for acceptable performance was $s_{\text{w-run}} < 0.25 \text{ TE}_{a}$ (TE$_{a}$ – total allowable error) (13).

Total imprecision. Three levels of commercially available control material were tested in duplicate, three times per day for 5 days (a total of 30 readings for each control). The control used included: Nova Biomedical StatStrip glucose controls: LEVEL 1 (range 2.4 – 4.1 mmol/L); LEVEL 2 (range 5.00 – 7.22 mmol/L); and LEVEL 3 (range: 14.0 – 17.9 mmol/L). The criterion for acceptable performance was $s_{\text{tot}} < 0.33 \text{ TE}_{a}$ (13).

Linearity

Nova StatStrip Glucose Linearity kit was used to examine analytical range limits. Linearity kit included 5 levels of glucose concentration: LEVEL 1 (range: 1.3-2.1 mmol/L); LEVEL 2 (range: 2.6-4.3 mmol/L); LEVEL 3 (range: 5.0-7.2 mmol/L); LEVEL 4 (range: 14.8-18.7 mmol/L); and LEVEL 5 (range: 25.2-31.9 mmol/L). We tested all glucose concentrations in triplicates and calculated mean values, which were plotted on the y-axis as observed values vs. values assigned by the manufacturer on the x-axis.

Table 1. Within-run and day-to-day imprecision for StatStrip Glucose Hospital Meter

<table>
<thead>
<tr>
<th>StatStrip Glucose Meter</th>
<th>Blood sample</th>
<th>Blood sample</th>
<th>Blood sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean glucose (mmol/L)</td>
<td>2.6</td>
<td>8.0</td>
<td>18.5</td>
</tr>
<tr>
<td>SD (mmol/L)</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
</tr>
<tr>
<td>CV (%)</td>
<td>1.9</td>
<td>2.1</td>
<td>1.9</td>
</tr>
<tr>
<td>Acceptable performance criteria</td>
<td>2.5</td>
<td>3.33</td>
<td></td>
</tr>
</tbody>
</table>

RESULTS

Precision

Comparison of methods was performed to estimate inaccuracy or systematic error (SE). A total of 481 capillary plasma samples were analyzed by the StatStrip Glucose Hospital Meter and AU400 analyzer.

Statistical analyses

All results were analyzed with MedCalc 9.4.2.0 statistical software (MedCalc Software bvba, Mariakerke, Belgium). For linearity experiment and comparison between analyzers, Passing-Bablok regression was used. For determination of bias both paired t-test and Wilcoxon test were used, as appropriate. For judging the performance of the method we used Westgard’s Method Decision Chart, with a total allowable error (TEa) criterion of 10% according to quality recommendations for laboratory glucose measurement (13,14). Performance of the StatStrip glucose meter in detecting hypoglycemia was assessed by a 2x2 table diagnostic test.
Linearity

Passing-Bablok regression showed no significant deviation from linearity, \( P>0.10 \) (Fig. 1). StatStrip glucose measurement was found to be linear from 1.3 to 31.9 mmol/L.

Figure 1. Linearity evaluation: scatter diagram and regression line for glucose measured on StatStrip Glucose Hospital Meter; standard value – assigned glucose values from Nova StatStrip Glucose Linearity Kit; observed values – measured glucose values from Nova StatStrip Glucose Linearity Kit.

Inaccuracy

The results obtained using the StatStrip Glucose Hospital Meter correlated well (\( r=0.9868 \)) with the laboratory routine procedure in a wide range of clinically relevant glucose concentrations (1.3-26.2 mmol/L) (Fig. 2).

The regression equation was \( y=-0.07073+1.0366x \) and determined bias from paired t-test was 0.17 mmol/L or 2.1% \((P<0.01)\). Bias was used as a measure of systematic error (SE) for the procedure under evaluation.

Additional analysis was undertaken to test the performance of the StatStrip glucose meter in detecting hypoglycemia. In a subset of samples with a measured plasma glucose of <3.2 mmol/L with routine method \((n=16)\), Wilcoxon paired test revealed statistically significant difference \((P<0.0012)\). However, median (2.55 vs. 2.30 mmol/L) and range values (1.6-3.1 mmol/L vs. 1.3-3.2 mmol/L) for the routine and StatStrip glucose results, respectively, did not confirm clinical significance of this finding. Statistical diagnostic testing revealed 100% specificity and 100% sensitivity in detecting hypoglycemia with StatStrip glucose meter.

Total error (TE) of the method was calculated from random error (RE) and systematic error (SE):

\[
TE_{\text{calc}} = 2.1\% \text{ (SE)} + 2.4\% \text{ (RE)} = 4.5\%,
\]

which was within designated criteria for laboratory glucose measurement (10%).

According to Westgard’s Method Decision Chart (13), whereby values for total allowable error, bias and random error are analyzed together, our method performance was rated as ‘good’ (not shown).

Since StatStrip Glucose Hospital Meter is intended to be used for monitoring therapy effects in inpatient settings, no verification of the reference interval(s), otherwise obligatory for method validation, was found to be relevant in this study.
DISCUSSION

StatStrip Glucose Hospital Meter is an easy-to-use point-of-care analyzer. Our evaluation of the analytical performance confirmed the compliance of the meter to the current quality requirements for laboratory glucose measurement (13,14). Both within-run imprecision and total imprecision met the criteria for acceptable performance. Calculated total error from random and systematic error(s) was 4.7%, which is much below the total allowable error (10%) for the laboratory methods of plasma glucose measurement.

The linearity range was wide, covering low glucose concentration level, which is of special interest for diabetic patients on insulin therapy for verifying hypoglycemic episodes. Our study revealed 16 hypoglycemic episodes in a total of 481 measurements, with a 100% compliance of the StatStrip glucose meter results to the laboratory routine measurement. Considering significant difference in the turnaround time between StatStrip glucose meter and laboratory routine procedure (6 seconds vs. 30 minutes) and clinical relevance of rapid detection and management of hypoglycemic episodes, StatStrip glucose meter was found to be a very reliable tool, particularly in patients suffering from hypoglycemia unawareness.

Apart from low turnaround time, StatStrip Glucose Hospital Meter has other advantages compared to determination of glucose in central laboratory. The amount of sample needed for 8-point glycemic profile is very small (<10 μL), which allows an improved comfort for diabetic patients. The connectivity to the laboratory information system (LIS) with bidirectional transfer of requisitions and results contributes significantly to the reduction of possible pre- and postanalytical errors in patient identification and result reporting.

Accuracy and specificity of the measurement is significantly improved due to new technology with hematocrit measurement and correction on the test strip (10). Our study samples included hematocrit levels ranging from 0.298-0.485 L/L, with no significant influence on the accuracy of the glucose measurement (not shown). However, further studies are needed to assess the possible influence of clinically extreme hematocrit levels on the StatStrip glucose measurement. The analytical performance of the StatStrip meter in tight glucose control in critically ill patients should also be verified in further studies. Results of this study indicated good method performance, with a total error within allowable limits for laboratory glucose measurement, which is a fundamental prerequisite in setting adequate treatment decisions and improve critically ill patient outcomes (8,15).

In conclusion, the StatStrip Glucose Hospital Meter is a simple, accurate, and reliable tool for assessing glycemic levels in inpatient management of diabetes mellitus.

REFERENCES


