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ORIGINAL ARTICLE

Analysis: New Point-of-Care Blood Glucose Monitoring System for the Hospital Demonstrates Satisfactory Analytical Accuracy Using Blood from Critically Ill Patients—An Important Step toward Improved Blood Glucose Control in the Hospital

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Abstract

Patients managed in the intensive care units (ICUs) and general wards of the hospital experience a high incidence of hyperglycemia, hypoglycemia, and glycemic variability, despite significant hospital resources devoted to glucose control. Optimized glucose meters and monitoring systems are required to improve the safety and efficacy of insulin delivery and glucose control in the hospital. Safe insulin dosing requires timely and accurate glucose measurements, especially during dynamic changes in nutrition, insulin sensitivity, and physiological stress. In the current issue of *Journal of Diabetes Science and Technology*, Mitsios and coauthors describe the analytical accuracy of the new Accu-Check® Inform II blood glucose (BG) monitoring system commercialized by F. Hoffmann-La Roche Ltd. The point-of-care glucose meter achieved the desired degree of accuracy and precision, as defined by Clinical and Laboratory Standards Institute POCT12-A3 guidelines when evaluated using venous blood from 600 critically ill patients from multiple ICUs at two medical centers. Venous whole blood samples were used to obtain glucose meter results in duplicate. The remaining blood sample was centrifuged to obtain plasma for central hospital laboratory testing using the hexokinase method within 5 min of meter testing. A total of 98.8% of the 1200 Accu-Check Inform II meter's glucose values were within ±12.5% (±12 mg/dl) of the mean laboratory glucose value, and 99.8% were within ±20% (±20 mg/dl), thus meeting the Clinical and Laboratory Standards Institute criteria. Future studies are required to evaluate the clinical performance of the new BG monitoring system in the intended-use patient populations and critical care environments, using arterial, peripheral venous, central venous, and capillary blood samples.

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Introduction

Medical and surgical patients experience a high incidence of hyperglycemia, hypoglycemia, and glycemic variability despite significant hospital resources devoted to glucose control.[1–12] Clinicians are challenged to dose insulin at the optimal time in relation to changes in nutrient intake, insulin sensitivity, hydration status, and organ function (renal, hepatic, gastrointestinal, and cardiovascular).[13–17] Accurate blood glucose (BG) measurements are necessary for safe and effective insulin therapy and calibration of near-continuous glucose monitoring systems for the hospital.[18–28]

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Abbreviations: (BG) blood glucose, (ICU) intensive care unit, (POC) point of care

Keywords: analytical accuracy, blood glucose monitoring system, glucose control, glucose meter, hospital, total measurement error

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The large RALS-Plus databases from Medical Automation Systems can be used to summarize the metrics of BG in hospitalized patients with diabetes and/or stress hyperglycemia.[29–31] Swanson and coauthors[32] analyzed data from 575 U.S. hospitals that used the Roche Accu-Chek® Inform meter/test strips and the RALs-Plus data management system to measure, record, and analyze 49,191,313 point-of-care (POC) BG measurements from 3,484,795 patients over a 12-month period. Only 24% of the POC BG measurements where obtained from ICU patients, while 76% were obtained outside of the ICU. The mean POC BG was 167 mg/dl for ICU patients and 166 mg/dl for non-ICU patients. The prevalence of hyperglycemia (>180 mg/dl) was 32.2% in ICU patients and 32.0% in non-ICU patients. The prevalence of hypoglycemia (<70 mg/dl) was 6.3% in ICU patients and 5.7% in non-ICU patients.[32]

Hyperglycemia in the hospital has been associated with an increased risk of fluid/electrolyte shifts, glycosuria, dehydration, wound infection, bacteremia, sepsis, myocardial/cerebral ischemia, congestive heart failure, deep vein thrombosis, and pulmonary embolism.[15–17,33–38] Glucose toxicity reduces the motility and phagocytic/cytotoxic functions of neutrophils, monocyte, and macrophages. Hyperglycemia causes increased platelet activation, adhesion, and plug formation.[39–43] Prolonged glycosuria can cause polyuria, decreased plasma volume, and intravascular dehydration. Insulin therapy causes glucose/water molecules to move out of the plasma and into the cells of skeletal muscle and adipose tissue. The treatment for hyperglycemia thus requires appropriate fluid management in addition to insulin therapy.[15–19]

Insulin-induced hypoglycemia may increase morbidity/mortality in hospitalized medical and surgical patients.[5,10,12,44–46] Clinicians evaluate each patient to weigh the potential clinical risks and benefits of intensive insulin therapy and tight glycemic control. Clinical guidelines recommend a 140 to 180 mg/dl target range to minimize hyperglycemia (>180 mg/dl) and avoid hypoglycemia (<70 mg/dl).[47–50] The fear of hypoglycemia determines the intensity of glucose monitoring and insulin therapy when patients are managed in the operating rooms, ICUs, and general wards of the hospital.[3,12,18]

Hypoglycemia may directly increase the morbidity/mortality of hospitalized patients or be a marker of illness severity in patients with malnutrition, metastatic cancer, bacteremia, sepsis, liver failure, acute kidney injury, and multiorgan failure.[5,10–12] The majority of hospitalized patients who experience hypoglycemia recover fully without an adverse event.[51,52] An increase in tissue blood flow may increase glucose delivery enough to meet the metabolic needs of the cells (mg/100 g tissue/min). The risk for an adverse event due to hypoglycemia may be the highest in patients who experience simultaneous hypoglycemia and decreased tissue blood flow. Prospective trials are required to determine whether avoidance of hypoglycemia in acutely ill patients will lead to an improvement in clinical outcome.

Safe and effective insulin therapy in the hospital therefore requires frequent, accurate, and timely BG measurements.[17–19,21,51–53] The hospital's central laboratory analyzer uses the hexokinase method to measure the concentration of centrifuged plasma glucose with high accuracy and precision but with a slow turnaround time. The 2011 recommendations for the desirable performance characteristics of a central laboratory glucose measurement include a coefficient of variation of <2.9%, an analytical bias or inaccuracy of <2.2%, and a total error of <6.0%.[54] The 2012 updated guidelines for central laboratory plasma glucose measurement is a coefficient of variation of <2.3% and an inaccuracy or bias <1.8%.[55] The total error is usually calculated as (absolute bias or inaccuracy) + (1.96 × standard deviation).[56]

The time delay from sample acquisition to providing the bedside clinician with an actionable BG measurement is an important source of total measurement error. The actual concentration of BG can significantly change when the measurement delay and turnaround time for reporting the result exceeds 15 min. Changing insulin therapy based on a patient's previous clinical state, rather than the current state, may cause insulin dosing errors, worsening BG control, and hypoglycemia.[57] The glucose meter or blood gas/glucose analyzer therefore needs to be located in close proximity to the patient.

Preanalytical error is a major contributor to total measurement error.[54,58–67] Hospitals should validate and standardize their methods for blood sample acquisition, handling, and glucose analysis to minimize preanalytical error.[18,27,28,65–68] Finger stick capillary samples can be affected by glucose on the skin surface, lancet size, hand position, finger blood flow, temperature, coagulation, and excess interstitial fluid/edema.[69–72] A standardized method for blood sample acquisition from a radial artery catheter produces reference BG measurements with the lowest standard deviation and few

outliers. Blood sampled from a stopcock or valve can be contaminated by infusion solutions. Central venous catheter blood samples can be contaminated or diluted from adjacent infusions.[18,27,28,55,67,68,71] Safe insulin therapy requires total BG measurement error to be as low as possible (preanalytical error + analytical error + time delay error = total measurement error).

More than 117,000 original Accu-Check® Inform BG monitoring systems are currently being used to manage patients in 2750 hospitals around the world. The Accu-Chek Inform II BG monitoring system utilizes a new meter and test strip design that overcomes many of the limitations of the original Accu-Check Inform BG monitoring system.[73,74]

The Accu-Check Inform II BG monitoring system evaluated by Mitsios and coauthors[75] exceeded the analytical accuracy and precision criteria, as defined by the Clinical and Laboratory Standards Institute POCT12-A3 guideline,[76] when evaluated using split venous blood samples from 600 patients managed in multiple ICUs at two academic medical centers. A total of 98.8% of the Accu-Check Inform II meter's glucose values were within ±12.5% (±12 mg/dl) of the mean laboratory analyzer's hexokinase glucose values, and 99.8% were within ±20% (±20 mg/dl).[75]

To achieve this degree of accuracy using ICU patient blood samples, the Accu-Check Inform II meter performed numerous quality checks with every test, enabling it to detect and compensate for common errors due to strip degradation and sample measurement conditions. The glucose meter used direct electric current to charge the working and reference electrodes, and alternating current impedance to confirm adequate sample volume and compensate for hematocrit.

Roche scientists developed a mutant variant of the quinoprotein glucose dehydrogenase enzyme to improve the assay's specificity for D-glucose, minimize error from interfering substances (maltose, galactose, triglycerides, ascorbic acid, and acetaminophen), and eliminate the errors from high and low oxygen concentrations. The glucose meter can use wireless communication to transfer BG measurement and time-stamp data directly into the hospital's electronic medical record. The Roche Diagnostics website nicely summarizes technical information and clinical trial data using the Accu-Check Inform II glucose monitoring system with a variety of blood sources (arterial, capillary, peripheral venous, or central venous), hospital environments (operating rooms, ICUs, and general wards), and patient populations.[73,74]

In conclusion, the Accu-Chek Inform II BG monitoring system produced satisfactory analytical accuracy and precision using peripheral venous whole blood samples from critically ill patients. This study moves us one step closer to removing the Food and Drug Administration label: "The performance of this system has not been evaluated in the critically ill." Additional clinical trials are required using arterial, peripheral venous, central venous, and capillary blood samples to evaluate the clinical performance of the Accu-Chek Inform II system when used by nurses in the intended-use patient populations and critical care environments of the hospital.

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Dr. Joseph currently serves, or has served, on the medical/scientific advisory boards of the following companies developing continuous glucose monitoring systems: Medtronic Diabetes Inc., Edwards Lifesciences Inc., DexCom Corporation, GluMetrics Inc., Echo Therapeutics, Flowsion LLC, and Becton Dickinson, Inc. The following companies have funded research at the Jefferson Artificial Pancreas Center: Medtronic Diabetes Inc., Edwards Lifesciences Inc., DexCom Corporation, GluMetrics Inc., Echo Therapeutics, Animas-Johnson & Johnson, St. Jude Medical, Teleflex Inc., and Hospira Inc. All funds are paid to Thomas Jefferson University.

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