

Point-of-Care Glucose Monitoring in a Critical Care Setting

Evaluation of a New Maltose Independent Chemistry Accu-Chek INFORM II, Nova StatStrip, and Abbott Medisense PXP

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Abstract: Maintenance of appropriate glycemic control (AGC) is known to reduce morbidity and mortality in critical-care patients [*N Engl J Med.* 2001;345(19):1359–1367; *Mayo Clin Proc.* 2004;79(8):992–1000; *N Engl J Med.* 2006;354(5):449–461]. Since point-of-care (POC) blood glucose test systems provide rapid results at the patient's bedside, they offer potential value in the maintenance of AGC protocols, but it is important to demonstrate that results are comparable to reference methodology and that they are not adversely affected by clinical scenarios, such as maltose therapy, hypernatremia and hyponatremia, and abnormal hematocrit. The aim of this evaluation was to determine whether the new Accu-Chek Inform II test strip for use with the Inform II POC blood glucose test system (Roche Diagnostics), Nova StatStrip (Nova Biomedical), and Medisense PXP (Abbott Diagnostics) demonstrated the required accuracy and precision to allow implementation of a AGC protocol in critically ill patients compared with the reference blood gas methodology currently in routine use within our critical care and intensive care areas (cobas b221; Roche Diagnostics). In addition, this study sought to determine whether these POC blood glucose test systems are suitable for use in patients receiving treatments that contain, or are metabolized to, maltose, and to determine the clinical implications of bias in patients with hypernatremia/hyponatremia and in patients with hematocrit values outside the manufacturer-specified limits. All POC blood glucose test systems within this evaluation demonstrated statistically significant correlation with reference methodology across the working range for critically ill patients. The performances of all POC systems tested are not adversely affected by the presence of maltose containing solutions.

All devices within this study showed no demonstrable bias in both hypernatremic and hyponatremic patient groups. A minimal positive bias was evident when hematocrit values were reduced, and a minimal negative bias when hematocrit levels were elevated. These clinical scenarios, however, would not preclude the POC system implementation in routine clinical practice.

Key Words: point-of-care testing, maltose, diabetes, accuracy, precision, critical care, appropriate glucose control, hematocrit, hypernatremia, hyponatremia

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Stress-induced hyperglycemia is common in hospitalized patients with or without diabetes.¹ The association between stress-induced hyperglycemia and adverse outcome has been observed in numerous patient groups ranging from patients ad-

mitted to the general ward² to those who have experienced myocardial infarction,³ stroke,⁴ surgery,⁵ burns, and head trauma.⁶

Maintenance of appropriate glycemic control (AGC) in diabetic and nondiabetic patients within surgical^{7,8} and medical⁹ intensive care units has shown a significant reduction in patient mortality and morbidity. Rapid lowering of blood glucose levels to within the range 4.4 to 6.1 mmol/L (80–100 mg/dL) and subsequent maintenance of normoglycemia are essential elements of the Leuven glucose control and maintenance protocol.

Rapid and precise methods for the determination of blood glucose levels are important for the clinical implementation of AGC. Point-of-care (POC) blood glucose test systems have been shown to be of value in the maintenance of AGC, offering rapid and precise results at the patient's bedside.¹⁰ However, careful considered evaluation of POC devices compared with reference methodology is imperative before implementation. It is also important to consider the limitations of the device to assess clinical risk.

Determination of blood glucose levels in patients who have received parenteral treatments that contain, or are metabolized to, maltose has been problematic in the past because of maltose interference with certain POC glucose test chemistries. Such maltose interference can lead to overestimation of blood glucose levels and may result in the inappropriate administration of insulin. It is important, therefore, to determine the effectiveness of POC test systems in the presence of maltose or maltose derivatives.

The aim of this evaluation was to determine whether the POC blood glucose test systems, Accu-Chek Inform II test strip in conjunction with the Inform II (Roche Diagnostics, Roche Rotkreuz, Switzerland), StatStrip (Nova Biomedical, Nova Waltham, Mass), and Medisense PXP (Abbott Diagnostics, Abbott Park, Ill), demonstrated the required accuracy and precision to allow implementation of a AGC protocol compared with reference blood gas methodology (cobas b221; Roche Diagnostics).

In addition, this study sought to determine whether the POC blood glucose test systems are suitable for use in patients receiving treatments that contain, or are metabolized to, maltose and to determine the clinical implications of bias in patients with hypernatremia/hyponatremia and in patients with hematocrit values outside the manufacturer-specified limits.

MATERIALS AND METHODS

Critical analysis of the Accu-Chek Inform II test strip in conjunction with Inform II, StatStrip, and Medisense PXP compared with reference blood gas methodology was divided into 4 clinically disparate evaluations, as follows:

- (1) Clinical evaluation of POC blood glucose test systems in critically ill patients

Two hundred paired random heparinized arterial blood samples were obtained from critically ill patients (from a cross section of clinical groups, including intensive and critical care, accident and emergency, and renal medicine).

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