

## Accuracy of a First-Generation Intravenous Blood Glucose Monitoring System in Subjects with Diabetes Mellitus: A Multicenter Study

Timothy Bailey, M.D., FACE, CPI,<sup>1</sup> Angela Gulino, M.S.,<sup>2</sup> Michael J. Higgins, M.B.A.,<sup>2</sup> Jacob Leach, B.S.,<sup>3</sup> Apurv Kamath, M.S.,<sup>3</sup> and Peter C. Simpson, M.Eng.<sup>3</sup>

### Abstract

#### **Background:**

Hyperglycemia and hypoglycemia in hospitalized patients have been associated with increased morbidity and mortality. Improvements in glucose monitoring technology may be helpful in the clinical management of critically ill patients with abnormal glucose levels. A first-generation intravenous blood glucose monitoring (IVBG) system was developed to facilitate glycemic control therapy in hospitalized patients. A nonrandomized, single-arm, multicenter study was performed to evaluate the safety and accuracy of the IVBG system in insulin-treated subjects with diabetes mellitus.

#### **Methods:**

The IVBG system is a bedside monitor that automatically measures venous blood glucose (BG) concentration. In this study, BG was measured every 7.5 min by the IVBG system. Reference samples [venous blood samples measured on the Yellow Springs Instruments (YSI) glucose analyzer] were drawn every 15 min during inpatient studies on days 1, 2, and 3. Fifty insulin-treated healthy volunteers with diabetes were studied, and a maximum of 72 reference samples were collected. Effectiveness was primarily evaluated by assessing the proportion of IVBG BG measurements within the 15 mg/dl or 20% criterion [15 mg/dl (for YSI <75 mg/dl) or 20% (for YSI ≥75 mg/dl)] compared with YSI. Adverse events and adverse device effects were evaluated.

#### **Results:**

A total of 95% of all IVBG values were within the 15 mg/dl or 20% criterion. The IVBG system BG measurement showed significant linear relationship with the laboratory YSI standard. Catheter insertion site irritation was mild and infrequent. No serious adverse events were reported. A total of 33% of the sensors were replaced during the 3-day use due to problematic IV lines or sensor/system errors.

#### **Conclusions:**

This clinical performance evaluation demonstrates that the IVBG system provides accurate and safe continuous BG measurements in healthy insulin-treated patients with diabetes.

*J Diabetes Sci Technol* 2013;7(6):1484–1491

**Author Affiliations:** <sup>1</sup>AMCR Institute Inc., Escondido, California; <sup>2</sup>Edwards Lifesciences, Irvine, California; and <sup>3</sup>Dexcom, San Diego, California

**Abbreviations:** (ADE) adverse device effect, (BG) blood glucose, (CEG) Clarke error grid, (ICU) intensive care unit, (IV) intravenous, (IVBG) intravenous blood glucose monitoring, (OLS) ordinary least squares, (SD) standard deviation, (YSI) Yellow Springs Instruments

**Keywords:** accuracy, glucose sensor, intravenous, near-continuous glucose monitoring, safety, YSI

**Corresponding Author:** Timothy Bailey, M.D., FACE, CPI, AMCR Institute Inc., 700 West El Norte Parkway, Suite 201, Escondido, CA; email address [tbaily@amcrinstitute.com](mailto:tbaily@amcrinstitute.com)