Use of a Novel Fluorescent Glucose Sensor in Volunteer Subjects with Type 1 Diabetes Mellitus

Thomas Peyser, Ph.D.,[1] Howard Zisser, M.D.,[2] Uzma Khan, B.A.,[2] Lois Jovanovič, M.D.,[2]
Wendy Bevier, Ph.D.,[2] Matt Romey, B.A.,[3] Jeff Suri, Ph.D.,[3] Paul Strasma, B.A., M.B.A.,[3]
Stephanie Tiaden, B.S.,[3] and Soya Gamsey, Ph.D.[3]

Abstract

Background:

Stress hyperglycemia in the critically ill has been found to be associated with increased morbidity and mortality. Studies have found significant improvements in morbidity and mortality in postsurgical patients whose glucose levels were closely maintained in the euglycemic range. However, subsequent studies, in particular the Normoglycemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation (NICE-SUGAR) study, found no improvement in subjects with tight glycemic control. In addition to differences in protocol design, patients in the tight glycemic control arm of the NICE-SUGAR study experienced high rates of hypoglycemia compared with other studies. One interpretation of the NICE-SUGAR study results is that it is difficult to achieve normal glycemia in critically ill patients with existing glucose monitoring technology. The purpose of the study reported here was to evaluate the safety and performance of a continuous intravascular glucose sensor that could be used in the future in critically ill patients.

Methods:

A first-generation prototype of an intravascular continuous glucose sensor was evaluated in 29 volunteer subjects with type 1 diabetes mellitus. The sensor operates on the principle of quenched fluorescence. The fluorescent emission from the sensor chemistry is nonlinear, resulting in improved accuracy in the hypoglycemic range. The duration of each study was 8 hours. Sensor output was compared with temporally correlated reference measurements made from venous samples on a laboratory glucose analyzer.

Results:

Data were obtained from 18 of the 29 subjects in the study. Data were analyzed retrospectively using a factory calibration plus a one-point in vivo calibration. The mean absolute relative difference was 7.97%, and 95.1% of all the points were in zone A of the Clarke error grid.

Conclusions:

This pilot study was the first use in human subjects of a prototype of the GluCath Intravascular Continuous Glucose Monitoring System (GluCath System). The GluCath System is based on a novel fluorescent sensor chemistry. The study found the GluCath System had a high level of accuracy as compared with a laboratory reference analyzer.

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Author Affiliations: [1]DexCom, Inc., San Diego, California; [2]GluMetrics, Inc., Irvine, California; and [3]Sansum Diabetes Research Institute, Santa Barbara, California

Abbreviations: (ICU) intensive care unit, (ISO) International Organization for Standardization, (MARD) mean absolute relative difference, (NICE-SUGAR) Normoglycemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation

Keywords: accuracy, fluorescence, hypoglycemia, intravascular continuous glucose monitor, sensor, tight glycemic control

Corresponding Author: Howard Zisser, M.D., Sansum Diabetes Research Institute, 2219 Bath St., Santa Barbara, CA 93105; email address hzisser@sansum.org