

Use of an Intravascular Fluorescent Continuous Glucose Sensor in Subjects with Type 1 Diabetes Mellitus

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Abstract

Background:

Stress hyperglycemia in the critically ill is associated with increased morbidity and mortality. Continuous glucose monitoring offers a solution to the difficulties of dosing intravenous insulin properly to maintain glycemic control. The purpose of this study was to evaluate an intravascular continuous glucose monitoring (IV-CGM) system with a sensing element based on the concept of quenched fluorescence.

Method:

A second-generation intravascular continuous glucose sensor was evaluated in 13 volunteer subjects with type 1 diabetes mellitus. There were 21 study sessions of up to 24 h in duration. Sensors were inserted into peripheral veins of the upper extremity, up to two sensors per subject per study session. Sensor output was compared with temporally correlated reference measurements obtained from venous samples on a laboratory glucose analyzer.

Results:

Data were obtained from 23 sensors in 13 study sessions with 942 paired reference values. Fourteen out of 23 sensors (60.9%) had a mean absolute relative difference $\leq 10\%$. Eighty-nine percent of paired points were in the clinically accurate A zone of the Clarke error grid and met ISO 15197 performance criteria. Adequate venous blood flow was identified as a necessary condition for accuracy when local sensor readings are compared with venous blood glucose.

Conclusions:

The IV-CGM system was capable of achieving a high level of glucose measurement accuracy. However, superficial peripheral veins may not provide adequate blood flow for reliable indwelling blood glucose monitoring.

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Abbreviations: (CGM) continuous glucose monitoring, (ISO) International Organization for Standardization, (IV-CGM) intravascular continuous glucose monitoring, (MAD) mean absolute difference, (MARD) mean absolute relative difference

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