

Evaluation of a Novel Continuous Glucose Measurement Device in Patients with Diabetes Mellitus across the Glycemic Range

Linda Morrow, M.D.,¹ Marcus Hompesch, M.D.,¹ Ann M. Tideman, B.S., C.C.R.A.,² Jennifer Matson, B.S.,² Nancy Dunne, R.N., B.S.N., M.P.H., C.C.R.A.,² Scott Pardo, Ph.D.,² Joan L. Parkes, Ph.D., C.C.R.A.,² Holly C. Schachner, M.D.,² and David A. Simmons, M.D.²

Abstract

Background:

This glucose clamp study assessed the performance of an electrochemical continuous glucose monitoring (CGM) system for monitoring levels of interstitial glucose. This novel system does not require use of a trocar or needle for sensor insertion.

Method:

Continuous glucose monitoring sensors were inserted subcutaneously into the abdominal tissue of 14 adults with type 1 or type 2 diabetes. Subjects underwent an automated glucose clamp procedure with four consecutive post-steady-state glucose plateau periods (40 min each): (a) hypoglycemic (50 mg/dl), (b) hyperglycemic (250 mg/dl), (c) second hypoglycemic (50 mg/dl), and (d) euglycemic (90 mg/dl). Plasma glucose results obtained with YSI glucose analyzers were used for sensor calibration. Accuracy was assessed retrospectively for plateau periods and transition states, when glucose levels were changing rapidly (approximately 2 mg/dl/min).

Results:

Mean absolute percent difference (APD) was lowest during hypoglycemic plateaus (11.68%, 14.15%) and the euglycemic-to-hypoglycemic transition (14.21%). Mean APD during the hyperglycemic plateau was 17.11%; mean APDs were 18.12% and 19.25% during the hypoglycemic-to-hyperglycemic and hyperglycemic-to-hypoglycemic transitions, respectively. Parkes (consensus) error grid analysis (EGA) and rate EGA of the plateaus and transition periods, respectively, yielded 86.8% and 68.6% accurate results (zone A) and 12.1% and 20.0% benign errors (zone B). Continuous EGA yielded 88.5%, 75.4%, and 79.3% accurate results and 8.3%, 14.3%, and 2.4% benign errors for the euglycemic, hyperglycemic, and hypoglycemic transition periods, respectively. Adverse events were mild and unlikely to be device related.

Conclusion:

This novel CGM system was safe and accurate across the clinically relevant glucose range.

J Diabetes Sci Technol 2011;5(4):853-859

Author Affiliations: ¹Profil Institute for Clinical Research, Inc., Chula Vista, California; and ²Bayer HealthCare LLC, Diabetes Care, Tarrytown, New York

Abbreviations: (APD) absolute percent difference, (ARD) absolute rate difference, (CGM) continuous glucose monitoring, (CI) confidence interval, (EGA) error grid analysis, (HbA1c) hemoglobin A1c, (SD) standard deviation, (YSI) Yellow Springs Instruments

Keywords: blood glucose, continuous glucose monitoring, glucose clamp method, hyperglycemia, hypoglycemia

Corresponding Author: Linda Morrow, M.D., Profil Institute for Clinical Research, Inc., 855 3rd Ave., Suite 4400, Chula Vista, CA 91911; email address linda.morrow@profil-research.com