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SYMPOSIUM

Evaluation of the Performance of a Novel System for Continuous Glucose Monitoring

Eva Zschornack, M.D.,[1] Christina Schmid, Ph.D.,[1] Stefan Pleus, M.S.,[1] Manuela Link, M.E.,[1] Hans-Martin Klötzer, Ph.D.,[2] Karin Obermaier, B.S.,[3] Michael Schoemaker, Ph.D.,[3] Monika Strasser, M.S.,[3] Gerhard Frisch, M.S.,[3] Günther Schmelzeisen-Redeker, Ph.D.,[3] Cornelia Haug, M.D.,[1] and Guido Freckmann, M.D.[1]

Abstract

Background:

The performance of a continuous glucose monitoring (CGM) system in the early stage of development was assessed in an inpatient setting that simulates daily life conditions of people with diabetes. Performance was evaluated at low glycemic, euglycemic, and high glycemic ranges as well as during phases with rapid glucose excursions.

Methods:

Each of the 30 participants with type 1 diabetes (15 female, age 47 ± 12 years, hemoglobin A1c 7.7% ± 1.3%) wore two sensors of the prototype system in parallel for 7 days. Capillary blood samples were measured at least 16 times per day (at least 15 times per daytime and at least once per night). On two subsequent study days, glucose excursions were induced. For performance evaluation, the mean absolute relative difference (MARD) between CGM readings and paired capillary blood glucose readings and precision absolute relative difference (PARD), i.e., differences between paired CGM readings were calculated.

Results:

Overall aggregated MARD was 9.2% and overall aggregated PARD was 7.5%. During induced glucose excursions, MARD was 10.9% and PARD was 7.8%. Lowest MARD (8.5%) and lowest PARD (6.4%) were observed in the high glycemic range (euglycemic range, MARD 9.1% and PARD 7.4%; low glycemic range, MARD 12.3% and PARD 12.4%).

Conclusions:

The performance of this prototype CGM system was, particularly in the hypoglycemic range and during phases with rapid glucose fluctuations, better than performance data reported for other commercially available systems. In addition, performance of this prototype sensor was noticeably constant over the whole study period. This prototype system is not yet approved, and performance of this CGM system needs to be further assessed in clinical studies.

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Author Affiliations: [1]Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH, Ulm, Germany; [2]HMKQ Quantitative Analytik - Chemometrie, Weinheim, Germany; and [3]Roche Diagnostics GmbH, Mannheim, Germany

Abbreviations: (BG) blood glucose, (CGM) continuous glucose monitoring, (MARD) mean absolute relative difference, (PARD) precision absolute relative difference

Keywords: accuracy, continuous glucose monitoring systems, hypoglycemia, POCT05-A, precision

Corresponding Author: Christina Schmid, Ph.D., Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm, Helmholtzstrasse 20, 89081 Ulm, Germany; email address *christina.schmid@uni-ulm.de*