

Accuracy of the SEVEN[®] Continuous Glucose Monitoring System: Comparison with Frequently Sampled Venous Glucose Measurements

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Abstract

Background:

The purpose of this study was to compare the accuracy of measurements obtained from the DexCom[™] SEVEN[®] system with Yellow Springs Instrument (YSI) laboratory measurements of venous blood glucose.

Methods:

Seventy-two subjects with insulin-requiring diabetes, aged 18–71, were enrolled in a multicenter, prospective single-arm study. All participants wore the SEVEN continuous glucose monitoring (CGM) system for one, 7-day wear period. Calibration with capillary finger stick measurements was performed 2 hours after sensor insertion and once every 12 hours thereafter. A subset of subjects (28) wore two systems simultaneously to assess precision. All subjects participated in one, 10-hour in-clinic session on day 1, 4, or 7 of the study to compare CGM measurements against a laboratory method (YSI analyzer) using venous measurements taken once every 20 minutes. Carbohydrate consumption and insulin dosing were adjusted in order to obtain a broad range of glucose values.

Results:

Comparison of CGM measurements with the laboratory reference method ($n = 2318$) gave mean and median absolute relative differences (ARDs) of 16.7 and 13.2%, respectively. The percentage was 70.4% in the clinically accurate Clarke error grid A zone and 27.5% in the benign error B zone. Performance of the SEVEN system was consistent over time with mean and median ARD lowest on day 7 as compared to YSI (13.3 and 10.2%, respectively). Average sensor time lag was 5 minutes.

Conclusions:

Measurements of the DexCom SEVEN system were found to be consistent and accurate compared with venous measurements made using a laboratory reference method over 7 days of wear.

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Abbreviations: (ADA) American Diabetes Association, (ARD) absolute relative difference, (CG-EGA) continuous glucose error grid analysis, (CGM) continuous glucose monitoring, (DCCT) Diabetes Control and Complications Trial, (FDA) Food and Drug Administration, (HbA1c) hemoglobin A1c, (ISF) interstitial fluid, (PARD) percent absolute relative difference, (PCV) percent coefficient of variation, (SD) standard deviation, (SMBG) self-monitored blood glucose, (T1DM) type 1 diabetes mellitus, (T2DM) type 2 diabetes mellitus, (YSI) Yellow Springs Instrument

Keywords: clinical accuracy, continuous error grid, continuous glucose monitoring, 7-day glucose sensor

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