

COMMENTS AND RESPONSES

Comparison of the Numerical and Clinical Accuracy of Four Continuous Glucose Monitors

Response to Kovatchev et al.

Kovatchev et al. (1) reported anomalous performance results of three continuous glucose monitoring (CGM) sensors during a hypoglycemia clamp study. The authors stated that “all three CGM sensors experienced periods of transient loss of sensitivity, particularly during hypoglycemia, identified as sensor readings holding steady at a very low glucose value (e.g., 2.1 mmol/l) . . .”

This study did not evaluate CGM systems per their intended use under normal therapeutic conditions. Instead, glucose was manipulated using a glucose clamp of intravenous glucose and insulin infusion. The hyperinsulinemic clamp method used is not likely to yield a response similar to that seen under normal therapeutic conditions. The flat response reported by

the sensors during hypoglycemia may have accurately reflected that subcutaneous tissue glucose was lower than blood glucose during the clamp study. More research is needed to evaluate the appropriateness of applying glucose clamps to the assessment of transcutaneous CGM devices before extrapolating these results to performance under intended clinical use conditions.

Furthermore, the investigators chose to use a hypoglycemia setting of 2.5 mmol/l, and accuracy was determined with reference to the ISO15197 Standard for Blood Glucose Meters. Two of the sensors (STS and Guardian) do not display readings below 2.2 mmol/l (2,3), yet the ISO Standard considers a sensor reading acceptable if it reads between 1.7 and 3.3 mmol/l at reference glucose of 2.5 mmol/l. Since STS and Guardian do not provide measurements for comparison across the acceptable range at 2.5 mmol/l, these sensors may have been falsely described as reporting unreliable measurements.

The authors do state that the DexCom device studied was the first-generation device. The new, FDA-cleared 7-day device (SEVEN) shows significantly improved performance in the detection of hypoglycemia and overall accuracy (mean absolute relative difference 15.7%) (4).

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DOI: 10.2337/dc08-1037

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