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SYMPOSIUM

Alarm Characterization for a Continuous Glucose Monitor That Replaces Traditional Blood Glucose Monitoring

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Abstract

Background:
Continuous glucose monitoring (CGM) devices available in the United States are approved for use as adjuncts to self-monitoring of blood glucose (SMBG); all CGM alarms require SMBG confirmation before treatment. In this report, an analysis method is proposed to determine the CGM threshold alarm accuracy required to eliminate SMBG confirmation.

Method:
The proposed method builds on the Clinical and Laboratory Standards Institute (CLSI) guideline for evaluating CGM threshold alarms using data from an in-clinic study of subjects with type 1 diabetes. The CLSI method proposes a maximum time limit of ±30 minutes for the detection of hypo- and hyperglycemic events but does not include limits for glucose measurement accuracy. The International Standards Organization (ISO) standard for SMBG glucose measurement accuracy (ISO 15197) is ±15 mg/dl for glucose <75 mg/dl and ±20% for glucose ≥75 mg/dl. This standard was combined with the CLSI method to more completely characterize the accuracy of CGM alarms.

Results:
Incorporating the ISO 15197 accuracy margins, FreeStyle Navigator® CGM system alarms detected 70 mg/dl hypoglycemia within 30 minutes at a rate of 70.3%, with a false alarm rate of 11.4%. The device detected high glucose in the range of 140–300 mg/dl within 30 minutes at an average rate of 99.2%, with a false alarm rate of 2.1%.

Conclusion:
Self-monitoring of blood glucose confirmation is necessary for detecting and treating hypoglycemia with the FreeStyle Navigator CGM system, but at high glucose levels, SMBG confirmation adds little incremental value to CGM alarms.

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Abbreviations: (BG) blood glucose, (CG-EGA) continuous glucose–error grid analysis, (CGM) continuous glucose monitoring, (CLSI) Clinical and Laboratory Standards Institute, (ISO) International Standard Organization, (SMBG) self-monitoring of blood glucose, (YSI) Yellow Springs Instrument

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