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ORIGINAL ARTICLE

Pilot Study of a Prototype Minimally Invasive Intradermal Continuous Glucose Monitor

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Abstract

Introduction:

The purpose of this study was to assess point accuracy, rate-of-change accuracy, and safety of a prototype, minimally invasive continuous glucose monitoring (CGM) device over a 12 h in-clinic study. The CGM system consisted of a wireless electronics module with a disposable glucose sensor attached to the bottom. The electronics module was affixed to the abdomen using an adhesive pad on the bottom of the disposable sensor housing.

Methods:

Two CGM sensors were inserted into the abdominal tissue (left and right) of 15 adults aged 26–67 years, 5 with normoglycemia, 5 with type 1 diabetes, and 5 with type 2 diabetes. Over a 12 h period, each participant was fed three meals. Reference venous blood samples were drawn at periodic intervals (12.4 ± 5.3 min), and glucose was measured at the bedside using a laboratory reference method. For each participant, a single plasma equivalent glucose concentration was used for retrospective sensor calibration.

Results:

A total of 1082 paired data points were obtained from 15 subjects and 25 of 30 sensors. Statistical analysis yielded a mean absolute relative difference of 12.6% and a mean absolute difference of 16.0 mg/dl. Continuous glucose error grid analysis showed the combined point and rate-of-change accuracy was 97.4% in zone A and 1.5% in zone B (98.9% A+B), with 1.1% erroneous readings.

Conclusions:

The prototype CGM system provided clinically accurate results 98.9% of the time and was well tolerated by participants, with little or no pain and no adverse events.

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Abbreviations: (CG-EGA) continuous glucose error grid analysis, (CGM) continuous glucose monitoring, (CRU) clinical research unit, (FDA) Food and Drug Administration, (HbA1c) hemoglobin A1c, (ISF) interstitial fluid, (MARD) mean absolute relative difference, (MAD) mean absolute difference, (P-EGA) point error grid analysis, (R-EGA) rate-of-change error grid analysis, (SMBG) self-monitoring of blood glucose, (YSI) Yellow Springs Instruments

Keywords: continuous glucose, error grid, interstitial, intradermal, minimally invasive

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