Accuracy and Stability of a Novel Subcutaneous Glucose Sensor

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Background and Aims

- CGM users value sensor performance characteristics such as accuracy, calibration frequency, and safety.
- We developed a new sensor and tested its accuracy with once-daily SMBG calibrations versus reference venous (YSI) values collected during clinic visits throughout 10 days of wear.

Methods

- Fifty subjects (49 with type 1 diabetes, mean±SD age 32.5±18.7 years) enrolled and 1 subject withdrew early.
- Subjects wore 1 sensor each, and used SMBG values for once-daily calibrations.
- CGM values were compared to YSI values collected on days 1, 2, 4, 7, and 10 of sensor wear.
- This analysis extends results in the abstract to include 994 paired YSI-CGM values from 49 subjects.

Results

- The overall percentage of sensor values within 15% of the reference value (or within 15 mg/dL [0.8 mmol/L] for reference values ≤100 mg/dL [≤5.6 mmol/L]) was *89.9% (95% CI, 87.9-91.7%)* and the analogous within-20% agreement rate was *96.1% (95% CI, 94.7-97.2%)%* (Figure 1).
- The overall mean ARD was *8.1% (95% CI, 7.6-8.5%)* (Figure 2). The median ARD was *6.8%*.
- Accuracy by all 3 metrics was best on Day 2.
- Surveillance error grid analysis (Figure 3) showed that almost all of the YSI-CGM paired points were in the "No Risk" or "Slight Risk" zones.
- The outlier point (YSI = 183 mg/dL, CGM = 70 mg/dL) would not prompt an insulin bolus if the CGM datum was used for an insulin dosing decision.

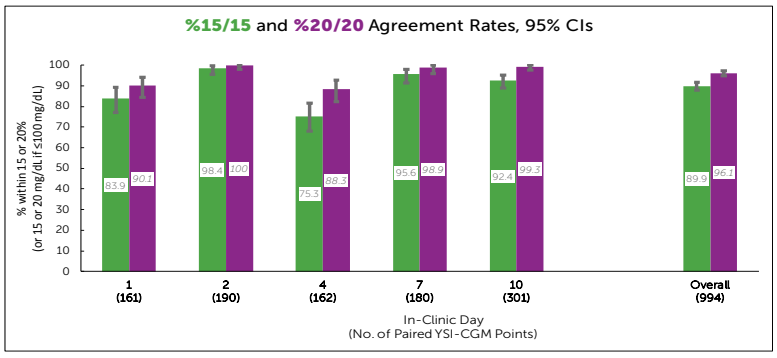

Figure 1. Within 15% and within-20% agreement rates

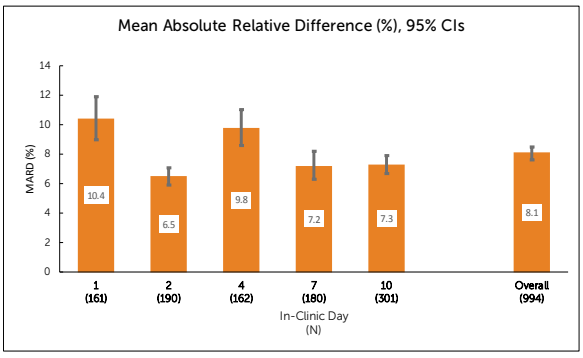

Figure 2. Mean absolute relative differences

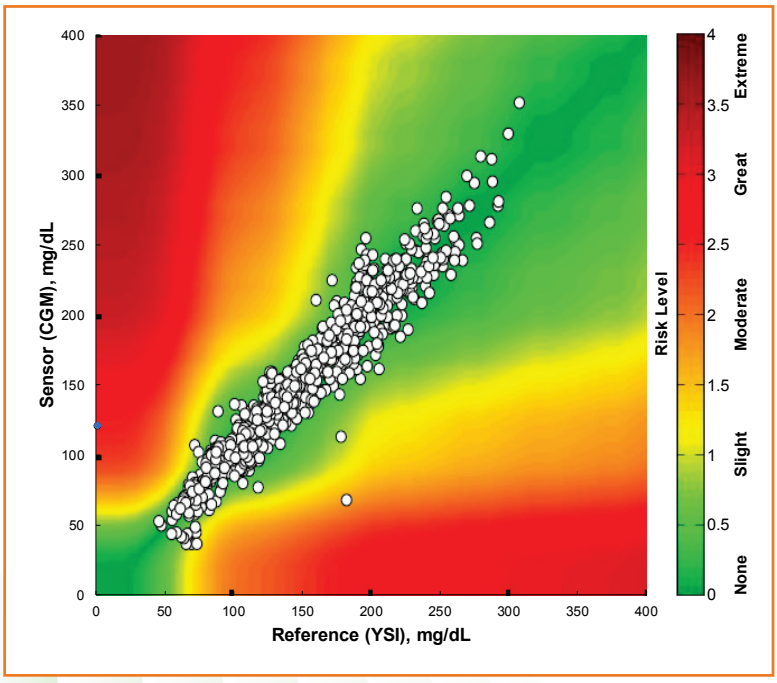

Figure 3. Surveillance error grid and risk categories

Summary

- The new system is accurate throughout its 10-day functional life.
- Once-daily calibrations may improve the user experience by reducing the need for SMBG.
- The surveillance error grid analysis supports the new system's potential utility for supporting diabetes management decisions and in closed-loop insulin delivery systems.

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