

Correlation Between Time in Range and Glucose Management Indicator with the Eversense CGM System

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BACKGROUND

The International Consensus on Time in Range, convened by ATTD in 2019, defined target ranges for CGM data¹. As a result, correlation of time below range (<70 mg/dL, <3.9 mmol/L and <54 mg/dL, <3.0 mmol/L), time in range (TIR, 70-180 mg/dL, 3.9-10.0 mmol/L) and time above range (>180 mg/dL, >10.0 mmol/L and > 250 mg/dL, 13.9 mmol/L) and HbA1c [or mathematical estimates of HbA1c, such as Glucose Management Indicator (GMI)] can be made. These correlations continue to validate the usage of CGM-derived glucometric data in clinical diabetes care.

The purpose of this analysis was to show the correlation between TIR, time above range, and time below range and GMI in data derived from 582 US users of the long-term implantable Eversense CGM system over 90 days. The Eversense CGM system has been commercially available in Europe and South Africa since 2016 and in the US since June 2018 for adults with diabetes. The glucometric data from the first 205 US users to complete a 90-day wear cycle showed a TIR of 62.3%². The accuracy of the system, measured by the mean absolute relative difference (MARD) against Yellow Springs Instrument (YSI) reference glucose analyzer, was 8.5%³⁻⁴.

METHODS

For this analysis, de-identified sensor glucose data from the Eversense Data Management System (DMS) was analyzed from 582 real-world commercial users who reached the end of the 90-day sensor wear period. The Glucose Management Indicator, the GMI, is a surrogate marker for HbA1c that can be derived mathematically from CGM data⁵. The GMI was correlated with the percent of sensor glucose values below range (<70 mg/dL, <3.9 mmol/L and <54 mg/dL, <3.0 mmol/L), in the target range (TIR, 70-180 mg/dL, 3.9-10.0 mmol/L) and above range (>180 mg/dL, >10.0 mmol/L and > 250 mg/dL, 13.9 mmol/L). Calculations were performed to determine the association between a 10% increase in TIR and time above range and the subsequent GMI value, and what TIR and time above range values were associated with a GMI of 7%.

RESULTS

The graphs show the correlation between TIR and time above range, and the GMI for the 582 users over the 90-day sensor wear period. As shown, GMI had a strong negative correlation with TIR with a R^2 value of 0.87. For time above range, the R^2 values were 0.96 for time >180 mg/dL (10 mmol/L), and 0.93 for time >250 mg/dL (13.9 mmol/L). For time below range (not shown in graph) the R^2 value was 0.20 for time <70 mg/dL (3.8 mmol/L) and 0.11 for time < 54 mg/dL (3.0 mmol/L).

A TIR increase of 10% (2.4 hours per day) was associated with a decrease in GMI of 0.44%. A time above range increase of 10% was associated with an increase in GMI of 0.40% for > 180 mg/dL (10 mmol/L). A TIR of 66.5% was associated with a GMI of 7%. A time above range of 29.0% was associated with a GMI of 7%.

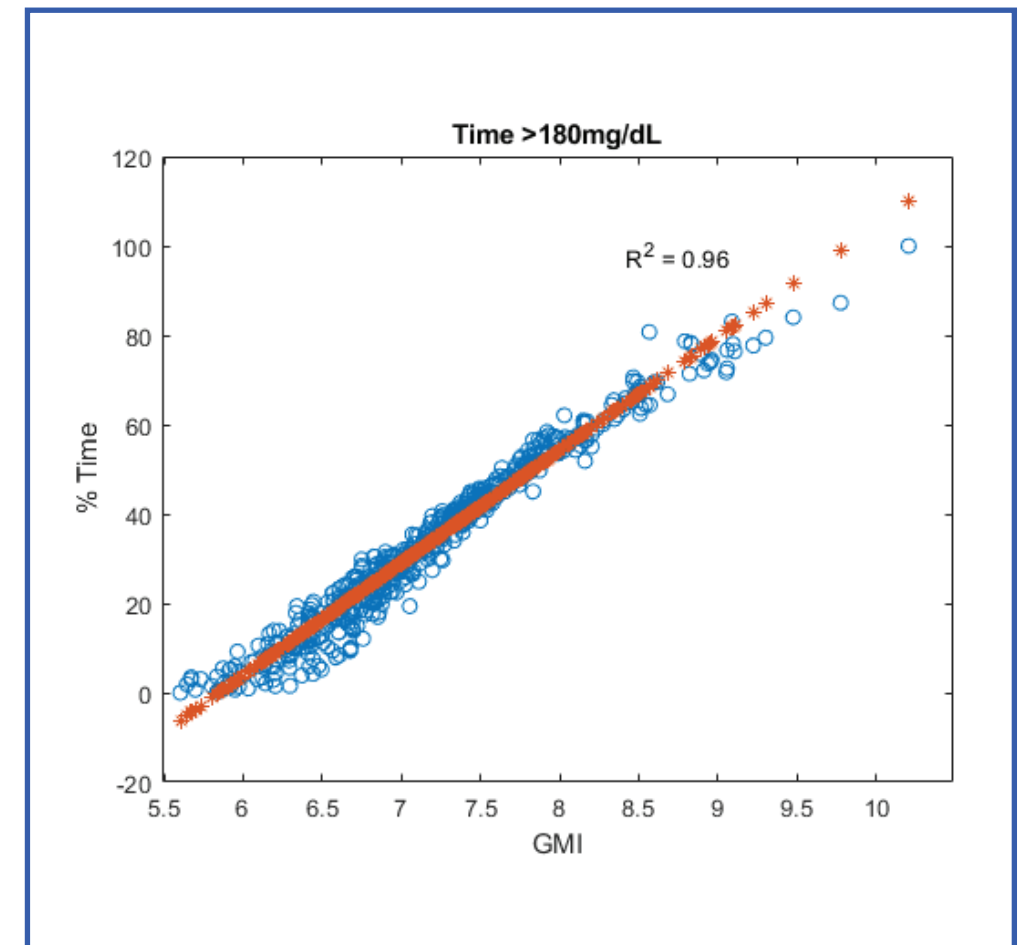
SUMMARY

- Data from a large cohort of Eversense CGM system users showed a strong correlation between TIR and GMI. There was an even stronger correlation between time above range and GMI, while there was a very weak association between time below range and GMI.
- The Eversense CGM glucometric data showed that a 10% increase in TIR (2.4 hours per day) was associated with a 0.44% decrease in GMI. This is very similar to what has been described previously by Beck et al of 0.5%⁶.
- The International Consensus on Time in Range recommended a TIR target of 70% and a time above range (>180 mg/dL, 10 mmol/L) target of 25%. These recommendations are supported by our data of 66.5% and 29.0%, respectively, that are associated with a GMI of 7%.
- These findings suggest that the Eversense CGM system is a valuable tool to obtain glucometric data that can be used to manage diabetes.

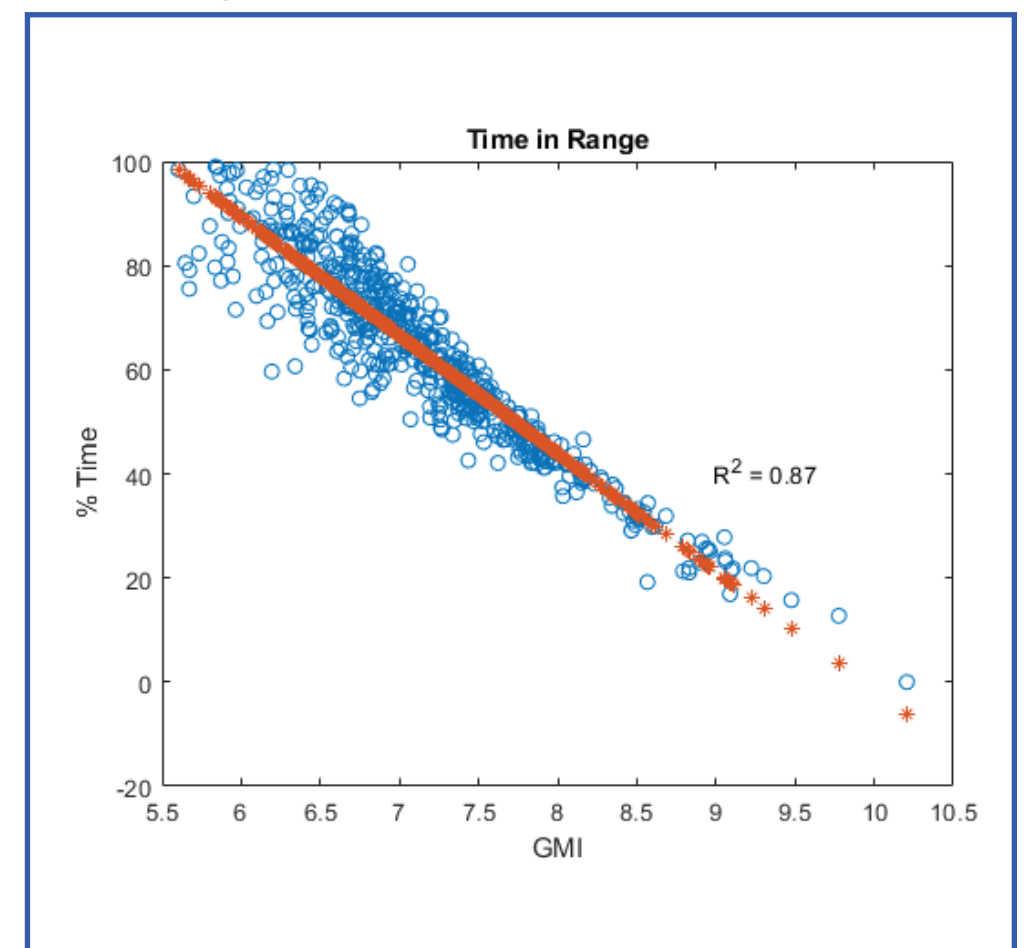
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Time > 180 mg/dL versus %GMI



Time in Range versus %GMI



CONCLUSIONS

Monitoring and targeting TIR, in addition to percent of sensor values in the hyperglycemic range, with the Eversense CGM system should help patients improve diabetes short- and long-term outcomes, particularly in between laboratory assessments of HbA1c.

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