Percent of Patients with Targeted Time in Range and Time in Hypoglycemia with the Eversense CGM System

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BACKGROUND

The Eversense® Continuous Glucose Monitoring (CGM) system (Senseonics, Inc., Germantown, MD) is the first long-term, 90-day duration implantable sensor which was approved by the Food and Drug Administration (FDA) in June 2018 for use in patients with diabetes 18 years of age and older. Three accuracy and safety trials (1-3) were performed showing optimal mean absolute relative difference (MARD) between sensor glucose (SG) data and the reference laboratory glucose values (Yellow Springs Instrument, YSI) of 8.5%, optimal mean absolute difference (MAD) performance in the hypoglycemia range (<70 mg/dL) of 7.2-7.6%, and hypoglycemia and hyperglycemia alert performance detection rates of 93% and 96%, respectively. The percent of time SG values were between 70-180 mg/dL (time in range, TIR, 3.9-10 mmol/L) was between 57-59% (data on file, Senseonics).

Analysis of the first 205 US commercial users who completed a 90-day sensor wear cycle has been recently published and results demonstrated accuracy and safety consistent with pivotal trial outcomes. Specifically, 62.3% TIR and 4.1% time in hypoglycemia (glucose values <70 mg/dL, <3.9 mmol/L) was observed with a median transmitter wear time of 83.6%[4].

The International Consensus on Time in Range which was organized by ATTD in 2019, defined targets for various glucose ranges for CGM data including TIR, time in hypoglycemia and time in severe hypoglycemia (glucose values <54 mg/dL, <3.0 mmol/L) (4)[3].

The objective of the current analysis was to determine the percent of users who met the International consensus targets in the first US users and compare those results to an expanded cohort.

METHODS

De-identified sensor glucose (SG) data from August 2018 to May 2019 in the Eversense Data Management System (DMS) were analyzed for the first 205 patients who reached a 90-day wear period on the Eversense CGM system. This analysis was expanded to August 2019. The percent of patients meeting the International Consensus recommended targets for the following glucose ranges was determined:

1. >70% TIR between 70-180mg/dL
2. <4% of time below 70mg/dL (3.9 mmol/L)
3. <1% of time below 54mg/dL (3.0 mmol/L)

RESULTS

Of the 205 patients, 129 identified as type 1, 18 as type 2, and 58 were unreported. Fifty were CGM naïve, 112 had prior CGM experience, and 43 were unreported. In the expanded cohort, 582 users had 90 days of sensor wear. The baseline characteristics of the 582-user cohort were consistent with the 205 cohort with 82% of users with type 1 diabetes and 65% prior CGM users. The mean sensor glucose (SG), standard deviation (SD), coefficient of variation (CV), glucose management indicator (GMI), and percent and time in minutes across glucose ranges over a 24-hour time period is shown in Table 1. The glucometric data showed that the mean SG, glycemic variability, %GMI, % time below ranges (< 70 mg/dL and <54 mg/dL <3.9 mmol/L and <3.0 mmol/L), % TIR and % time above ranges (>180 mg/dL and >250 mg/dL >10 mmol/L and >13.9 mmol/L) were consistent between the original 205 cohort and the expanded 582 cohort. Specifically, both cohorts nearly met the International Consensus clinical target for % time in hypoglycemia of <4%, TIR of 62.8% was comparable to the highest reported for stand-alone CGM[5, 6] and the wear time exceeded the recommended international consensus clinical target of >70%.

The percent of users achieving the TIR and both times in hypoglycemia clinical targets for the 205-user cohort and the 582-user cohort is shown in Table 2. With regard to TIR, 42 and 37% of users in the initial and expanded cohort achieved that target, respectively. The time in hypoglycemic targets was met in over 60% of users in both cohorts.

Table 1: Glucometric Data of the First 205 Eversense Patients Compared to an expanded Cohort of 582 for the 24-Hour Time Period

Glucometric	205 Cohort Mean (SD)	582 Cohort Mean (SD)
SG mg/dL [mmol/L]	161.8 (33.3) [9]	161.1 (30.6) [8.9]
SD mg/dL [mmol/L]	57.4 (14.8) [3.2]	57.1 (15.1) [3.2]
CV	0.35 (0.06)	0.35 (0.07)
GMI%	7.18 (0.80)	7.16 (0.73)
	% SG Mean (SD)	% SG Mean (SD)
<54 mg/dL [<3 mmol/L]	1.2 (1.8)	1.2 (1.7)
<70 mg/dL [<3.9 mmol/L]	4.1 (4.1)	4.0 (4.1)
70-180 mg/dL [3.9 - 10 mmol/L]	62.3 (19.0)	62.8 (17.8)
>180 mg/dL [>10 mmol/L]	33.5 (20.3)	33.2 (18.8)
>250 mg/dL [>13.9 mmol/L]	11.6 (12.8)	10.7 (11.4)

Table 2: Percent of Users Achieving International Consensus CGM Glucose Targets in Range and in Hypoglycemia for 205 and 582 Cohort

Target	Percent users at target (205 Cohort)	Percent mean time in target (205 Cohort)	Percent users at target (582 Cohort)	Percent mean time in target (582 Cohort)
≥70% time in range (70-180 mg/dL) (%) [3.9 to 10 mmol/L]	42.0	62.3	37.3	62.8
<4% of time <70 mg/dL (%) [<3.9 mmol/L]	61.5	4.1	63.6	4.0
<1% of time <54mg/dL (%) [<3.0 mmol/L]	63.9	1.2	64.9	1.2
All three metrics (TIR, TBR)	23.4	NA	22.9	NA

NA=not applicable

CONCLUSIONS

In the real-world setting, the Eversense CGM System was shown to assist patients in achieving recommended glucose goals regarding hypoglycemia, with ~64% of patients avoiding what has been defined as an excess of very low SG values. In addition, over 40% achieved targeted TIR. These data support the use of the first long-term implanted CGM system as a viable tool to manage diabetes.

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