The Glycemic Outcomes of the Eversense CGM System in an Expanded Cohort of 582 Real-World US Commercial Users

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BACKGROUND

The first long-term implantable Eversense CGM system (Senseonics Inc., Germantown, Maryland, USA) was approved for US commercialization in June 2018. Accuracy and safety have been demonstrated in multiple clinical trials and real-world studies.[1-5] The first US real-world data publication reported on 205 users with a 90-day sensor wear cycle.[1] Using the same analytic methodology, a larger user base of 582 was subsequently analyzed.

METHODS

De-identified sensor glucose (SG) data from the Eversense data management system from August 2018 to August 2019 were analyzed for the first 582 patients who reached their initial 90-day wear period and compared to the first 205 patients previously reported. Demographic data was obtained at CGM system registration including age, gender, diabetes type and prior CGM use. The mean SG, standard deviation (SD), median interquartile range (IQR), coefficient of variation (CV), glucose management indicator (GMI), and percent and time in minutes across glucose ranges were computed for the 24-hour time period. Median transmitter wear time was also assessed.

RESULTS

The makeup of the 582 cohort was similar to the 205 cohort with ~1/3 naïve CGM users and ~80% T1D and 52% male (Table 1). Glucometric data were similar between the larger cohort and the original population (Table 2). The mean SG was 162 and 161 mg/dL (9 and 8.9 mmol/L), CV was .35, GMI was 7.18% and 7.16%, and time in range was 62 and 63% in the 205 and 582 user groups, respectively. Mean percent SG <70mg/dL (<3.9 mmol/L) approached the targeted value of <4% (4.2 and 4.0% for 205 and 582 users, respectively). Median transmitter wear time was 84 and 85% for first and expanded user cohorts, respectively.

DISCUSSION

Evaluation of an expanded cohort of U.S. commercial Eversense CGM system users shows that the CGM metrics and transmitter wear time results observed with the first commercial users were predictive of that observed in an almost 3-fold increase in the number of users.

- The expanded cohort nearly met the international consensus clinical target for percent of SG readings in hypoglycemia (<4%)[6].
- TIR of 62.8% is comparable to the highest reported for non integrated CGM systems although no head-to-head studies have previously reported these metrics.[7, 8]
- Wear time exceeds recommended international consensus clinical target of >70% of the time.

Table 1: Demographics of Expanded 582 Cohort

Characteristic	Total (N=582)
Age, mean (SD)	43.9 (13.9)
Male sex, n (%)	305 (52%)
Diabetes type	
Type 1 (% of reported)	368 (82%)
Type 2 (% of reported)	81 (18%)
Unreported	133
Prior CGM use (% of reported)	341 (65%)
Dexcom	172 (50%)
Libre	76 (22%)
Medtronic	93 (27%)
SMBG use (% of reported)	181 (33%)
Unreported prior CGM use	60

Table 2: CGM Metrics and Transmitter Wear Time in U.S. Commercial Users in First Users Compared to an Expanded Cohort

	24-hour time period Mean (SD) **205** Users		24-hour time period Mean (SD) **582** Users	
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)	Time in Minutes 24-hour time period	% SG Mean (SD)	Time in Minutes 24-hour time period
<54 mg/dL [<3 mmol/L]	1.2 (1.8)	18.0	1.2 (1.7)	17.1
<70 mg/dL [<3.9 mmol/L]	4.1 (4.1)	59.7	4.0 (4.1)	57.5
70-180 mg/dL [3.9 - 10 mmol/L]	62.3 (19.0)	897.7	62.8 (17.8)	904.9
>180 mg/dL [>10 mmol/L]	33.5 (20.3)	482.6	33.2 (18.8)	477.7
>250 mg/dL [>13.9 mmol/L]	11.6 (12.8)	166.7	10.7 (11.4)	154.7
Median Percent Wear Time	83.6 190 Users		84.9 541 Users	

CONCLUSIONS

This data shows that the promising glycemic outcomes and system usage obtained in the first 205 users was sustained in a larger cohort of US commercial Eversense CGM system users. These real-world outcomes suggest the Eversense CGM system is a useful tool for diabetes management.

References

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