USABILITY, SAFETY, AND BENEFITS OF MULTIPLE SENSOR USE OF A LONG-TERM IMPLANTABLE CONTINUOUS GLUCOSE MONITORING SYSTEM

Xiaoxiao Oliver Chen, PhD; Suresh Addaguduru, MS; Colleen Mdingi, MS; Ravi Rastogi, PhD; Andrew DeHennis, PhD
Senseonics, Incorporated, Germantown, MD, USA

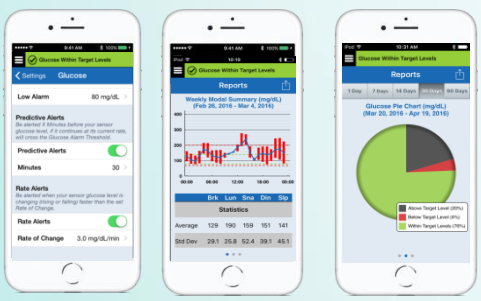
Introduction

Continuous glucose monitoring (CGM) over prolonged period can be linked to hypoglycemia prevention. The Eversense® CGM System consists of an implanted fluorescence-based glucose sensor that lasts up to 90 days, a wearable smart transmitter, and a mobile app to display real-time glucose readings. The first generation Eversense system is commercially available in Europe. This abstract presents user adherence, adverse events, and glucose variability results of multiple sensor use from the EU registry database.

Eversense CGM System

The Eversense CGM utilizes a long-term glucose sensor powered by an wearable smart transmitter through a wireless inductive link.

Smartphone App



- The App (iOS and Android) enables viewing of the real-time glucose readings, trends, and history through a touch interface
- Customizable alert settings with notifications
- Reports of daily glycemic variations that can be shared or exported

Wearable Smart Transmitter

- Attached via daily replaceable adhesive patch
- Removable and replaceable without having to change sensor
- Provides discreet on-body alerts via vibration motor
- Water resistant and lightweight
- Charging time of 15 minutes (approx.)

Methods

A group of 50 Eversense users in Europe who had three cycles of sensor use or were currently on their 3rd sensor (up to 270 days) between September 2016 and September 2017 were included in this analysis. For each individual 90-day sensor use, the percent wear time, number of device or procedure related adverse events (AEs), the average glucose, and percent time in ranges were tabulated.

Results

A total of ~13,500 sensor wear days were analyzed. High user adherence was sustained in each subsequent sensor use. Five AEs were reported during the 1st sensor use and 2 were reported during the 2nd and 3rd sensor use, respectively. No serious AEs were reported. While average glucose between sensor use was maintained, numerical reduction in percent time in both hypoglycemia and severe hypoglycemia was observed.

	1st Sensor Use	2nd Sensor Use	3rd Sensor Use
Percent Wear Time (%)	86.7 (SD 15.5)	88.6 (SD 9.8)	85.0 (SD 13.6)
Total Number of AEs (Number of Users)	5 (4)	2 (1)	2 (2)
Average Glucose (mg/dL)	162.6 (SD 22.8)	165.1 (SD 23.7)	165.2 (SD 25.9)
Percent Time in Severe Hypoglycemia (<54 mg/dL) (%)	1.7 (SD 3.1)	1.2 (SD 1.1)	1.1 (SD 1.2)
Percent Time in Hypoglycemia (<70 mg/dL) (%)	5.1 (SD 5.1)	4.4 (SD 2.7)	4.0 (SD 3.1)
Percent Time in Target (70-180 mg/dL) (%)	58.6 (SD 15.1)	58.2 (SD 14.4)	59.0 (SD 15.5)
Percent Time in Hyperglycemia (>180 mg/dL) (%)	36.3 (SD 14.8)	37.4 (SD 15.2)	37.0 (SD 16.3)

Conclusion

The Eversense CGM system has been demonstrated to be safe over repeated insertions, promotes adherence and shows a trend to decreased hypoglycemia and severe hypoglycemia.

Contact Information:
Name: Andrew DeHennis
Email: Andy.Dehennis@senseonics.com

Senseonics™