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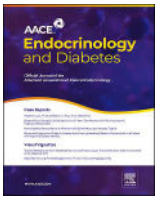

Case Report

Severe Hyperglycemia due to Calibration Misuse in an Eversense-365 Implantable Continuous Glucose Monitoring System

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ABSTRACT

Background: Continuous glucose monitoring (CGM) systems have transformed diabetes management by improving glycemic outcomes and providing real-time glucose data. Accuracy is commonly assessed by using metrics such as mean absolute relative difference. Implantable CGM systems, including Eversense-365, have demonstrated high accuracy and safety when used in accordance with recommended protocols.
Objective: To describe a case of clinically significant CGM inaccuracy resulting from improper user calibration and to highlight associated safety implications.
Case Report: An adult with a 24-year history of type 1 diabetes complicated by microvascular and macrovascular disease, hypoglycemia unawareness, and mild cognitive impairment was using an implantable CGM system. Initially, sensor readings closely matched capillary glucose values when appropriate fingerstick calibration techniques were followed. However, the patient subsequently used CGM-derived glucose values in place of capillary measurements for calibration. This practice led to progressively inaccurate sensor readings, yielding falsely reassuring glucose values and delaying recognition of clinically significant hyperglycemia.
Discussion: This case highlights a critical safety consideration in implantable CGM systems that rely on user-dependent calibration. Even with otherwise high-performing technology, improper calibration practices can significantly compromise accuracy. As CGM systems become increasingly integrated into automated insulin delivery platforms, user-related factors may introduce risk if proper technique is not consistently followed.
Conclusion: Improper calibration of implantable CGM systems can lead to clinically significant inaccuracies and delayed recognition of hyperglycemia. Reinforcing patient education, adhering to recommended calibration protocols, and selecting patients thoughtfully are essential to ensure the safe and effective use of these devices.

Introduction

The Eversense-365 continuous glucose monitoring (CGM) system is an implantable device approved for adults with insulin-treated diabetes, offering long-term glucose monitoring with a sensor lifespan of up to 1 year. Its performance depends on regular capillary glucose calibration, initially daily and then weekly throughout sensor wear. In clinical studies, the system demonstrated high accuracy, with a mean absolute relative difference of 8.8% across 365 days of use.[1]

Current standards of care emphasize the growing role of CGM in diabetes management, including its integration with automated insulin delivery (AID) systems and its use to guide insulin dosing.[2] As implantable CGM systems are increasingly considered for integration with AID systems, accurate calibration, adherence to calibration protocols, and appropriate patient selection are essential.

Abbreviations: AID, automated insulin delivery; CGM, continuous glucose monitoring.

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Case Presentation

We report a case of inaccurate glucose readings from an implantable CGM system due to an improper calibration technique. The patient was an adult with type 1 diabetes, complicated by microvascular and macrovascular disease and hypoglycemia unawareness. Her complications include diabetic retinopathy, peripheral neuropathy, gastroparesis, nephropathy, coronary artery disease with prior angioplasty, and a history of ischemic right middle cerebral artery stroke. At the time of occurrence, she had been living with type 1 diabetes for 24 years. She was initiated on an implantable Eversense-365 CGM system to simplify glucose monitoring. She has a history of mild cognitive impairment but remains independent in her activities of daily living. She resides with a caregiver who assists with diabetes management; however, she remains her own legal guardian. She had previously discontinued insulin pump therapy, including an AID system, due to unsafe device management. She had prior experience using transcutaneous CGM systems without difficulty.

Initial CGM usage was consistent with capillary glucose values when appropriate fingerstick calibration techniques were followed. She was utilizing the One Touch Verio Flex blood glucose meter to obtain finger stick glucose values for CGM calibration. Following implantation, CGM metrics were initially comparable to her prior system use. Over the subsequent months, CGM-reported time-in-range progressively increased, reaching 87% to 92%. The recommended CGM target for most nonpregnant adults with diabetes is a time-in-range of >70%, which is a defined glucose range of 70–180 mg/dL.[2]

On June 16, 2025, routine laboratory testing revealed severe hyperglycemia with a serum glucose of 786 mg/dL and HbA1c >16%. At the time of blood draw, CGM readings were in the low 100 mg/dL range. Point-of-care capillary glucose testing confirmed marked hyperglycemia ("HI"), prompting immediate discontinuation of the CGM-guided insulin dosing and resumption of capillary glucose monitoring.

Review of glucometer data demonstrated regular capillary glucose monitoring through late April 2025, with no recorded measurements in May or early June until presentation. Calibration logs revealed that glucose values entered for calibration closely matched concurrent CGM readings and were absent from glucometer downloads, indicating that CGM-derived values, rather than capillary glucose measurements, were used for calibration. Review of her electronic health record indicated that she had not received tetracycline or mannitol during this time of CGM inaccuracy.

Over time, using CGM-derived glucose values in place of capillary measurements for calibration created a closed feedback loop that progressively reinforced inaccurate sensor readings. Because the Eversense algorithm uses calibration inputs to adjust sensor accuracy, this process delayed the recognition of true hyperglycemia.

The patient was unable to reliably perform required fingerstick calibrations despite prior education and caregiver involvement. Given the risk of recurrent severe hyperglycemia, the device was discontinued. She resumed capillary glucose monitoring for insulin dosing and was later transitioned back to a transcutaneous CGM system.

Discussion

CGM accuracy is influenced by both device performance and user-dependent factors, including calibration technique. Most currently available transcutaneous CGM systems are factory-calibrated and cleared by the U.S. Food and Drug Administration to guide insulin dosing without routine confirmatory fingerstick blood glucose testing. In contrast, the implantable Eversense-365 CGM requires periodic calibration with capillary blood glucose measurements to maintain sensor accuracy and is U.S. Food and Drug Administration-cleared for nonadjunctive insulin dosing when used as directed. Implantable CGM systems, such as Eversense-365, have demonstrated strong accuracy when calibration protocols are followed appropriately.[1–4] Calibration is performed using capillary blood glucose values obtained with any commercially available blood glucose meter.[5]

Various CGM systems are susceptible to substance-specific interference that may affect sensor accuracy. For example, acetaminophen and hydroxyurea have been reported to cause falsely elevated glucose readings with certain Dexcom and Medtronic Guardian CGM systems, whereas high-dose ascorbic acid (vitamin C) may falsely elevate glucose readings with the FreeStyle Libre system.[2] In contrast, the Eversense system has demonstrated potential interference from tetracycline and mannitol at therapeutic plasma concentrations.[6] Unlike these chemically mediated interferences, the present case demonstrates a calibration-related error resulting from inappropriate use of sensor-derived glucose values for calibration, leading to prolonged masking of severe hyperglycemia.

This case illustrates a clinically significant safety risk when calibration requirements are not followed. Using CGM-derived values for calibration creates a feedback loop that reinforces inaccurate sensor readings, resulting in false reassurance and delayed recognition of severe hyperglycemia. Device-related adverse events associated with CGM systems may arise from both technical and user factors, underscoring the importance of appropriate use and monitoring.[7]

Patient selection is an important consideration when initiating implantable CGM systems. Individuals with cognitive limitations, challenges in performing fingerstick testing, or difficulty adhering

Highlights

- Implantable continuous glucose monitoring (CGM) systems require strict adherence to capillary glucose calibration to maintain accuracy
- Use of CGM-derived values for calibration can create a feedback loop, resulting in progressively inaccurate glucose readings
- Calibration errors may lead to falsely reassuring CGM values and delayed recognition of severe hyperglycemia
- Patients with cognitive or self-management limitations may not be appropriate candidates for calibration-dependent CGM systems
- Discordance between CGM data and clinical presentation should prompt immediate verification with capillary glucose

Clinical Relevance

Calibration misuse in implantable continuous glucose monitoring (CGM) systems can result in clinically significant inaccuracies and delayed recognition of hyperglycemia. Clinicians should prioritize patient selection, reinforce calibration education, and verify discordant CGM readings to ensure safe integration of these devices into diabetes management.

to calibration requirements may be at increased risk for improper use. Even with caregiver support and prior CGM experience, the correct calibration technique may not be consistently maintained. Although this patient had previously demonstrated difficulty managing diabetes technology, she had successfully used a transcutaneous CGM before transitioning to an implantable CGM system, suggesting that calibration requirements, rather than CGM use alone, contributed to the observed error.

As CGM systems are increasingly integrated into AID platforms and used for nonadjunctive insulin dosing, calibration errors may have broader implications for insulin delivery and patient safety.[2] This underscores the need for careful patient selection, comprehensive education, ongoing reinforcement of device-specific requirements, and continued monitoring of CGM accuracy over time.

Conclusion

This case highlights the importance of proper calibration technique and careful patient selection when using the implantable Eversense-365 CGM system. Clinicians should assess a patient's ability to meet the cognitive and behavioral demands of implantable CGM systems, reinforce calibration education, and maintain vigilance for discordance between CGM and capillary glucose data. Unexpected improvements in CGM-derived metrics should prompt verification of calibration practices to ensure patient safety, particularly as this CGM technology becomes more integrated into AID systems.

Ethics Statement

Written informed consent was obtained from the patient, who is her own legal guardian, for publication of this case report.

Disclosure

The author has no conflicts of interest to disclose.

Declaration of Generative AI and AI-Assisted Technologies in the Writing Process

The author used an artificial intelligence–based language tool to assist with editing for clarity and readability. All content was reviewed and verified by the author.

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