Case Study: Successful Use of a Single Subcutaneous Continuous Glucose Monitor Sensor for 28 Days in a Patient with Type 1 Diabetes

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PRESENTATION

R.F. is a 48-year-old white man with type 1 diabetes since age 24. He was initially seen at the Utah Diabetes Center in Salt Lake City on 15 September 2006. The patient had been treated with NPH insulin, 2 units at bedtime; ultralente insulin, 3 units twice a day; and lispro insulin, 2–3 units at each meal. The patient corrected elevated blood glucose levels with 1 unit of lispro for blood glucose readings > 200 mg/dl and about 2 units of lispro for blood glucose readings > 300 mg/dl. His hemoglobin A1c (A1C) was 9.2%, and he described losing control of his diabetes progressively through the years.

The patient often developed nocturnal hypoglycemia, most likely as a result of the combination of NPH and ultralente insulins taken at bedtime, and his blood glucose levels often dropped by 50–80 mg/dl through the night. The fear of nocturnal hypoglycemia and the patient's inability to control postprandial blood glucose levels were very frustrating to him. He had no evidence of microvascular complications. His blood pressure and lipids have always been within the normal range.

R.F.'s basal insulin regimen was changed to detemir insulin twice daily, and he was also given an insulin-to-carbohydrate ratio to determine lispro doses at mealtimes and a correction scale to aggressively correct hyperglycemia. He also received intensive diabetes education. By 7 April 2007, his A1C was 7.8%, and he had gained much more confidence as his blood glucose levels remained stable through the nights.

The patient then decided to purchase a continuous glucose monitor (CGM) system (Medtronic MiniMed Guardian REAL-Time Continuous Glucose Monitoring System). The patient was instructed on the use of the sensor system by the diabetes education team at the Utah Diabetes Center. He continued to monitor his blood glucose levels four to six times per day. He found that he was able to aggressively dose insulin at meals based on anticipated carbohydrate intake and to correct even mild hyperglycemia throughout the day. His A1C had improved to 5.5% when measured on 11 October 2007.

The patient described replacing the subcutaneous sensor used in his CGM system only every 10–14 days, instead of the recommended 3 days. He reported minimal to no local skin irritation and described the accuracy of the system as excellent, even after using a single sensor for at least 1 week. During his clinic visit on 11 October 2007, he described using his current subcutaneous glucose sensor for 28 consecutive days.

The patient's CGM data was downloaded, and the weekly sensor reports by week over the 4-week period are displayed in Table 1. The patient typically provided four to six valid calibrations per day with his glucose meter. The mean absolute difference in glucose levels between the CGM readings and the glucose meter results remained excellent, in the 15–19% range for the entire month during which he had worn the same subcutaneous glucose sensor. On exam, the sensor site showed minimal surrounding erythema with no discharge or tenderness.

QUESTIONS

1. What is the current Food and Drug Administration (FDA)-approved length of use for a subcutaneous glucose sensor?
2. Might subcutaneous glucose sensors be used safely and effectively for longer periods of time than currently recommended?
3. Could more patients with diabetes benefit from this sophisticated but

Table 1. Performance Characteristics of a Single Subcutaneous Continuous Glucose Sensor Over 4 Weeks

Week	Number of Valid Paired Calibrations	Mean Absolute Difference (%)
1	33	15
2	34	16.3
3	34	15.7
4	29	19.3

expensive technology by extending the length of use of subcutaneous glucose sensors and thereby reducing costs?

COMMENTARY

This case highlights an important consideration in the use of CGM systems and raises questions regarding the longevity of subcutaneous glucose sensors. It is well known that diabetes is associated with numerous vascular complications that are clearly related to the duration and severity of hyperglycemia. With improvements in this patient's insulin regimen, a decreased in A1C of 1.4 percentage points was achieved. The use of the CGM system allowed the patient to more aggressively treat even mild hyperglycemia and further reduced his hemoglobin A1C by 2.3 percentage points.

The Diabetes Control and Complications Trial demonstrated that intensive therapy resulting in an average A1C of 7.2% reduced the risk of retinopathy by 76%, nephropathy by 50%, and neuropathy by 60% compared to standard therapy resulting in an average A1C of 9.1%.[1] In addition, lower A1C values risk of nonfatal myocardial infarction, stroke, or death from cardiovascular disease by 57 %.[2] Thus, lowering R.F.'s A1C by more than 3 percentage points was enormously beneficial. His glycemic control was clearly improved by the addition of the CGM system.

This case also raises questions about the longevity of subcutaneous glucose sensors. Currently, the Medtronic Guardian REAL-Time CGM system sensor is FDA-approved for 3 days of continuous wear.[3] The DexCom sensor is approved for 7 days of continuous wear, and the FreeStyle Navigator is approved for 5 days of continuous wear.[4,5] But can these sensors be worn for longer periods of time than their current FDA approvals and still remain accurate? R.F. wore his sensor for 28 days and maintained a 15–19% mean absolute difference in glucose values. This is similar to the accuracy reported between the Yellow Springs Instrument glucose analyzer and the Guardian REAL-Time readings (mean absolute difference 19.7 ± 18.4%).[3]

The main barrier to obtaining a CGM system is the initial cost for the system and, more importantly, the resistance of insurance companies to pay for this new technology. The initial out-of-pocket expense ranges from $800-$1,200 with monthly costs for sensors ranging $240 to $450.

However, the total annual economic cost of diabetes in 2007 was estimated to be $174 billion.[6] Medical expenditures comprised a large portion of these costs totaling $116 billion, including $58 billion to care for chronic diabetes-related complications.[6] In fact, one of every five health care dollars is spent caring for someone with diagnosed diabetes, while one in ten health care dollars is attributed to diabetes.[6] As A1C increases, medical costs increase. For every increase of 1 percentage point from 6% to 10%, cumulative charges increase by 4, 10, 20, and 30%, respectively.[7] Improvements in long-term glycemic control with CGM, albeit at a significant initial cost, may more than offset the costs of treating the chronic complications of diabetes.

Many of our patients have observed their sensors working accurately for longer periods than the FDA-approved time limits. We have not discouraged this practice. If the practical, functional life of a subcutaneous glucose sensor is generally longer than currently believed, monthly costs associated with CGM will obviously be much lower, increasing access to this important technology for many patients. Studies investigating the possibility of longer sensor life spans are much needed.

CLINICAL PEARLS

There are three CGM systems available for use (Medtronic Guardian REAL-Time Continuous Glucose Monitoring System, FreeStyle Navigator Continuous Glucose Monitoring System, DexCom Seven Continuous Glucose Monitoring System)

Individual subcutaneous glucose sensors are currently approved for 3-day (Medtronic Guardian), 5-day (FreeStyle Navigator), and 7-day (DexCom Seven) use.

The initial cost of a CGM system is roughly $800–1,200 and ongoing monthly costs are $240–350 for continuous use.

Studies are needed to determine whether subcutaneous continuous glucose sensors may remain safe and accurate for longer periods than current FDA-approved time limits.

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