Continuous Glucose Monitoring System — Useful but Expensive Tool in Management of Diabetes

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Abstract

Until recently, self monitoring of blood glucose (SMBG) was the only tool used for monitoring blood glucose levels. The limitation of SMBG is that it cannot continuously monitor blood glucose levels. In this paper, we present our initial experience with the continuous glucose monitoring system (CGMS) in three different clinical situations. With reduction in cost and further refinement in technology, CGMS could become a valuable tool for clinical practice and research studies in diabetes. ©

Introduction

Recent reports from various trials such as Diabetes Control and Complications Trial (DCCT)[1] have demonstrated the importance of tight glycemic control in the prevention of complications of diabetes. Indeed, it is now accepted that the cost of treating the complications of diabetes far exceeds that of regular monitoring and therapy of diabetes.

Self monitoring of blood glucose (SMBG) has today become an integral part of the diabetes management. However, SMBG only gives blood sugars at the different points of time when the patient chooses to test the blood sugar. It is possible that there could be occasions during the day or night when the blood sugars may go very high or low and these peaks and valleys can be completely missed even in patients who perform SMBG regularly. Often, Somogyi syndrome or rebound hyperglycemia following an episode of hypoglycemia is clinically suspected but difficult to prove because of the non-availability of continuous blood glucose monitoring. The advantage of monitoring blood glucose levels continuously are therefore obvious but till recently, this had remained the diabetologist's dream.

Continuous ambulatory blood pressure monitoring and holter monitoring have been available for quite some time. There has been a long felt need for a similar device which could monitor blood glucose on a continuous basis and give us an insight into the trend of the blood glucose levels on a 24 hour basis. After decades of research, such systems have finally seen the light of day. Continuous glucose monitoring system, (CGMS) is one of the first such devices to become commercially available to monitor glucose levels on a continuous basis for upto 72 hours. It was approved by the Food and Drugs Administration (FDA), U.S.A. in June 1999 and it has been successfully used in several centres abroad for evaluation of diabetic patients during the last one to two years.

The CGMS unit consists of a glucose sensor, which is inserted into the subcutaneous tissue of the body and left in place for upto 72 hours. This sensor senses the interstitial fluid glucose levels electrochemically every 10 seconds and records an average value every 5 minutes and gives 288 values per day. These glucose values are recorded on a monitor, which is the size of a pager. Finger-stick blood glucose values are also entered into the monitor for calibration purpose and a minimum of four values per day are needed for accurate calibration. Events like exercise, food intake, insulin delivery and hypoglycemic episodes can also be entered in the monitor. After 72 hours, the sensor is removed and the data from the monitor is downloaded into a PC, which gives a continuous graph of the glucose values of the previous 3 days with the finger-stick values and the events plotted in time.

CGMS was introduced at the M.V.Diabetes Specialities Centre, Gopalapuram, Chennai in August 2002 and we started using this technology to evaluate patients whose blood sugars are poorly controlled despite optimal treatment. In this report, we present our initial experience with CGMS which we believe is the first report of CGMS from India.

Case 1

This is a 45 year old lady with Type 2 diabetes mellitus of 10 years duration. She was highly motivated to control her diabetes and was doing regular SMBG based on which she adjusted her insulin doses. She was on oral agents in addition to three insulin injections per day. However she complained of repeated hypoglycemic symptoms and blood tests revealed fluctuating fasting plasma glucose values with consistently

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high postprandial values and several episodes of hypoglycemia.

After initially adjusting her dosage of insulin with short acting insulin injections with breakfast and lunch, and a mixture of short and intermediate acting insulins with dinner, we started her on CGMS.

Fig. 1a shows the first day's CGMS profile. It shows a low sugar reaction around 2 to 3 AM followed by a spurt in blood sugar around 6 AM which further rises to a high value of around 300 mg by about 10.AM. As the morning insulin took effect, there was an another hypoglycemic episode around noon with another surge after lunch. The dose of intermediate insulin at night was reduced and this prevented the early morning hypoglycemia the next day as shown in Fig. 1b. However the day time control was still not sufficient. After the morning dose was readjusted, a much smoother profile of blood glucose levels were obtained on Day 3 (Fig. 1c).

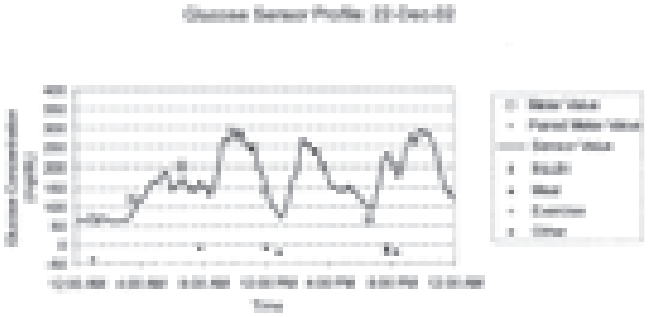

Fig. 1a : Day 1 of Case 1.

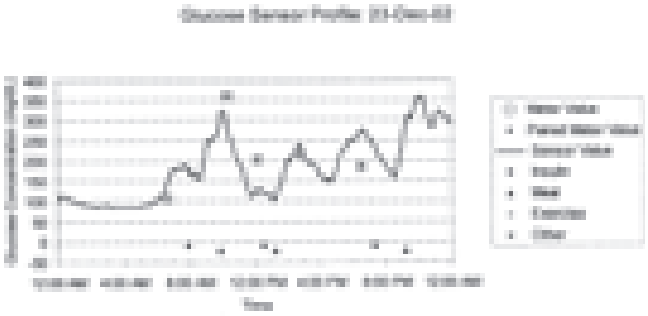

Fig. 1b : Day 2 of Case 1.

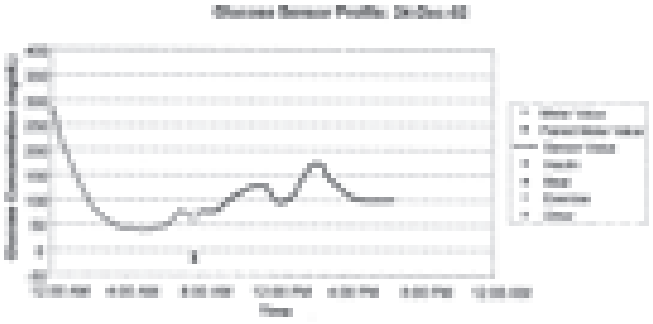

Fig. 1c : Day 3 of Case1.

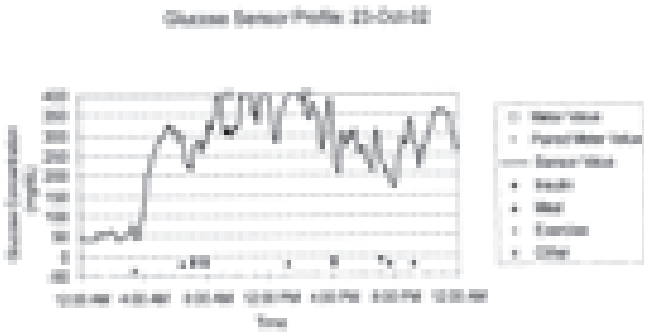

Fig. 2a : Day 1 of Case 2.

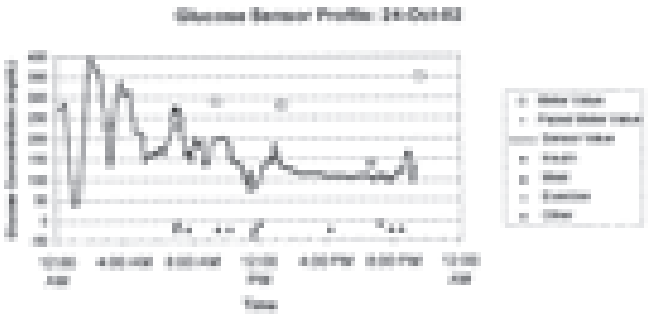

Fig. 2b : Day 2 of Case2

CASE 2

This is a 12 yr old female child with recently detected Type 1 diabetes mellitus. She was on once a day premixed insulin at bed time which was started by a local physician before she came to our centre. Her HbA1c was 18%. Fig. 2a shows the atrocious control of diabetes with hypoglycemic episodes in the night and day time with sugars hovering between 200 to over 400 mg/dl (note upper limit of CGMS is 400 mg/dl). She was started on a TDS insulin regime. After addition of the morning and noon doses of insulin, the daytime control considerably improved (Fig. 2b). However, she still had an episode of hypoglycemia at midnight followed by a Somogyi syndrome which was corrected the next day by adjusting the night dose of insulin (data not shown).

In this case, CGMS proved to be a great motivating tool for the parents and the girl to accept the TDS insulin regime and on follow-up after 4 months her HbA_1c had dropped to 7.5%.

CASE 3

This patient is a late onset Type 1 diabetes mellitus of 11 years duration who was unable to get his HbA_1c below 10% even with multiple injections and different insulin regimens. During his first visit his HbA_1c was 11.8%. He was motivated and advised to use continuous subcutaneous insulin infusion(CSII). He was admitted for demonstration and initiation of CSII. On the day of admission, CGMS was started (Day 1) while he was on a four times a day insulin regime and this was continued on Day 1 and Day 2. Fig. 3a (Day 1) and b (Day 2) shows how bad his control was even with four times

Fig. 3a : Day 1 of Case 3.

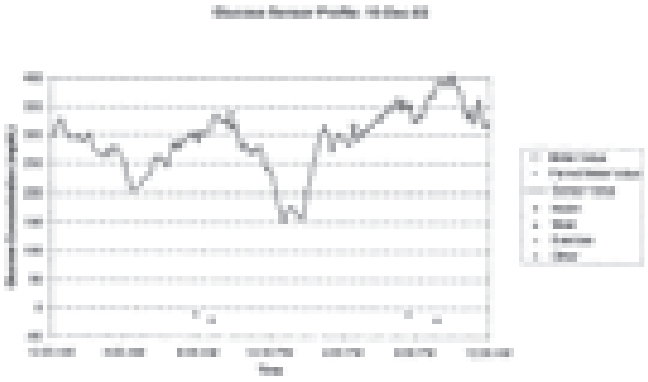

Fig. 3b : Day 2 of Case 3.

insulin per day. CSII was initiated around 8 PM on Day 2. He was started on a fixed basal rate with dual wave boluses of Lispro insulin with meals. While on CSII, patient was also allowed to take his usual food and was taught to adjust his bolus doses by himself based on SMBG values. With initiation of CSII, the glycemic control got better and the fluctuations were largely eliminated and the blood sugars became near normal (Fig. 3c and 3d).

After seeing the results of the CGMS, the patient was very much convinced about the usefulness of CSII and for the past several months has been using CSII and his HbA_1c has improved considerably.

Discussion

In this report, we presented three different clinical situations where we have used CGMS and derived benefit to achieve better control of diabetes. We have now used CGMS in many more patients and have found it to be a very useful tool both to learn more about the patient's diabetic status and also to educate and motivate the patient to achieve tight control. Table 1 summarizes some of the situations where we believe CGMS may be useful.

Table 1 : Clinical uses of CGMS

1. Continuous assessment of glycemic trends and patterns
2. Detection of unexpected and unrecognized hypoglycemia.
3. Checking adequacy of treatment regimens
4. To study the glycemic indices of various food stuffs
5. For achieving better programming of the insulin pump (CSII).

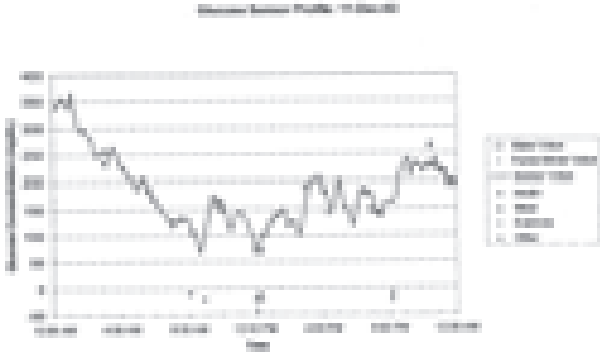

Fig. 3c : Day 3 of Case 3.

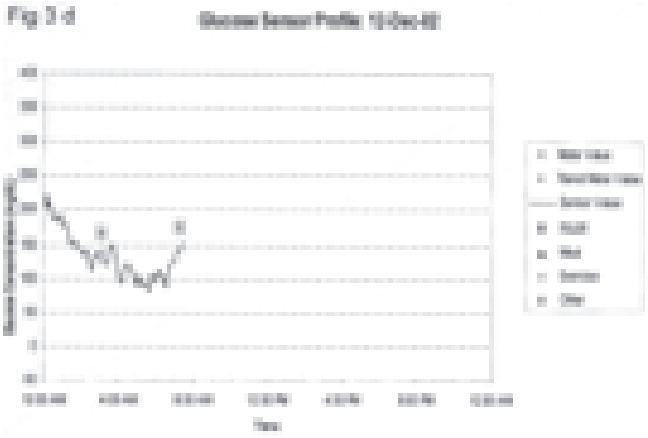

Fig. 3d : Day 4 of Case 3.

CGMS is a relatively new inclusion into the armamenterium of monitoring devices and the experience with its usage is rather limited. We reveiwed the current literature which carry reports on the utility of CGMS. Kaufman[2] and Bode and Hirsch[3] used the CGMS on Type 1 diabetic subjects and concluded that CGMS helped to identify glycemic pattern in them and was useful to adjust therapy. Boland and Tomborlane[4] used the CGMS graphs to educate and motivate young Type 2 diabetic patients about healthy lifestyle and diet practices. Moghissi and Mestman[5] have reported that in Type 2 diabetic patients, CGMS revealed postprandial hyperglycemia and noctural hypoglycemia which was missed by conventional testing. Jovanovic[6] monitored glycemic status in gestational diabetic patients and states that CGMS findings are useful in educating the patient about behaviour modifications that are needed to achieve tight glycemic control and prevent macrosomia.

Thus it is clear that CGMS is very helpful in many situations where we need to achieve good control. However, it is currently expensive, especially in a developing country like India. It requires at least four SMBG readings per day which need to be entered into the CGMS monitor against which the sensor calibrates the readings done. Unless four SMBG readings are done, the profile obtained may not be reliable and this adds to the cost of the treatment.

The CGMS unit itself currently cost around Rs. 2.5 lakhs and the sensor costs around Rs 4200/- and hence a 3 day

study wth CGMS would prove to be quite costly for the average Indian.

Another major drawback of CGMS is that the glucose profile needs to be downloaded on to a computer only after disconnecting the sensor from the patient. Therefore, it does not give a real time display of the trend which will assist us to adjust therapy immediately and the results are available only after the CGMS is disconnected after 72 hours. Thus if further modifications need to be done based on the CGMS findings and this needs to be documented, the patient needs to undergo CGMS again which increases the cost factor considerably. Finally the upper limit of blood sugar in CGMS is currently 400 mg/dl and if this could be set at a much higher level, it would be possible to detect wide fluctuations of blood sugar.

In conclusion, CGMS has made the dream of the diabetologist to measure glucose levels continuously a reality. It is to be hoped that in the years to come, reduction in the costs and further improvements in technology would ensure more widespread use of this potentially exciting method of continuously monitoring glucose levels. We need to identify those patients who will be benefited by CGMS. As it is a new technology, the health care professionals using CGMS have to become familiar with it and feel comfortable to use it on patients. The cost of any new technology is inevitably high and CGMS is no exception. There is no doubt that the information that CGMS gives is very valuable in improving the treatment and quality of life of the patient and his/her own understanding of the diabetes, which outweighs the cost involved, atleast in selected patients.

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