Continuous blood glucose monitoring: Implications for a district general hospital

Jane Young

Blood glucose is traditionally monitored discontinuously. People with diabetes who fail to achieve glycaemic control by this means may benefit from continuous glucose monitoring using a biosensor system. About 18 months ago, the diabetes centre at Broomfield Hospital, Chelmsford, was loaned one such system by the manufacturer. The device is a minimally invasive 48-hour continuous glucose monitor. To date, 30 people with diabetes have worn the device. This article evaluates the usefulness of the device in informing practice in a district general hospital. It reports the experiences of people wearing the device, and the benefits of wearing the device from the perspectives of both the person with diabetes and the health professional.

Many people with diabetes are required to monitor their capillary blood glucose regularly in order to effect treatment changes or adjust their insulin regimens. This form of testing is also used in conjunction with glycated haemoglobin (HbA_{1c}) as a means of determining the efficacy of treatment. For many people, this is adequate; however, this methodology offers only a brief glimpse of the overall picture and provides inadequate information about glycaemic excursions for some people with diabetes (Boland et al, 2001).

In recent years, biosensor systems have been developed; these enable a much more detailed overview of glycaemic excursion. The performance and reliability of these devices have now reached levels that allow them to be utilised in clinical practice, as opposed to the confines of a laboratory. This form of monitoring is known as continuous glucose monitoring (CGM). There are a number of such systems available, but the one evaluated here is the GlucoDay.

The device is a microdialysis system that allows estimation of blood glucose levels via sampling of subcutaneous fluid every 3 minutes over 48 hours. The device comprises a small box attached to tubing, which is connected to a microfibre inserted in the subcutaneous fat of the abdomen. Glucose in the subcutaneous fluid generates an electrical charge, which is measured by the device and converted into a glucose reading. The concentration of glucose in subcutaneous fluid has been shown to correlate with capillary and venous blood glucose levels (Maran et al, 2002).

The purpose of this article is to evaluate the usefulness of the device as a means of informing practice in a district general hospital. It also reports the experiences of people wearing the

Article points

1. People with diabetes who fail to achieve glycaemic control by conventional means may benefit from continuous glucose monitoring using a biosensor device.
2. This small, anecdotal, evaluation of one such device in 30 people attending a hospital diabetes clinic found benefits for both people with diabetes and health professionals.
3. The majority of people who used the device made changes to the way they managed their diabetes.
4. The main factor limiting use of the device was time: with current resources only one slot per week could be allocated to the process.

Key words

- Continuous glucose monitoring
- Biosensor
- Evaluation

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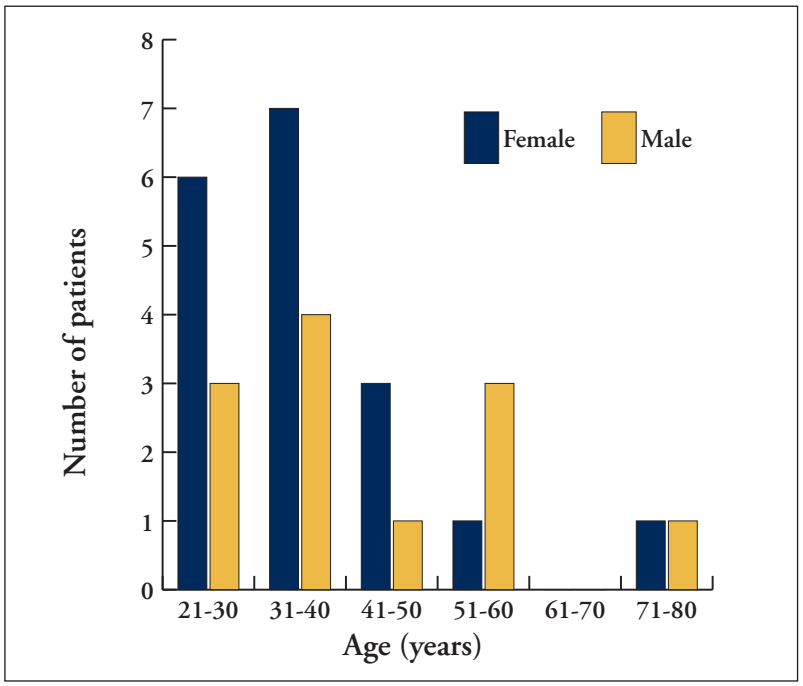

Figure 1. Age range and gender split among the 30 people with diabetes who have worn the device.

device, and the perceived benefits of wearing the device from the perspective of both the person with diabetes and the health professional.

Literature review

CGM has been utilised in a number of clinical settings, e.g. to detect abnormal patterns of glycaemia and to gain information that could be used to alter diabetes management in children with type 1 diabetes (Kaufman et al, 2001). Kaufman and colleagues claim that they were able to improve HbA_{1c} from a mean of 8.6±1.5% at baseline to 8.4±1.3% over a 3-month period in a sample of 47 paediatric patients (P=0.03). Although an improvement of 0.2% in mean HbA_{1c} is not of great clinical significance, the maximum change possible would demonstrate a considerable improvement in glycaemic control. CGM has also been used to detect asymptomatic and nocturnal hypoglycaemia in children and adolescents (Guerci, 2004).

Further applications include the management of insulinomas (Baldeweg et al, 2003), detection of hypoglycaemia following pancreatic transplantation (Esmatjes et al, 2003) and recording of postprandial glucose changes in people with type 1 diabetes (Manuel-y-Keenoy et al, 2004). (As insulinomas are rare, the applications most useful for clinical practice at the local level are those that relate to the management of people with type 1 diabetes.)

Some investigators argue that although CGM is useful for detecting unrecognised hypoglycaemia, it is no better than traditional frequent finger-stick testing combined with more intensive patient follow-up (Chico et al, 2003). Others have used it to guide therapy adjustment in people with type 1 diabetes (Boland et al, 2001).

It is claimed that CGM can help to reduce the duration of hypoglycaemia when compared with therapy adjustments guided by self-monitoring of blood glucose alone (Tanenberg et al, 2004). The counter argument is that it cannot be used as a replacement for blood glucose meters (Guerci et al, 2003).

Table 1. Criteria for inclusion in the sample of people offered the opportunity to wear the continuous glucose monitor (participants were not required to meet all the criteria unless they had type 2 diabetes).

- Type 1 diabetes (or type 2 diabetes if all other criteria met)
- Suspected unrecognised hypoglycaemia
- Looking for enhanced information to inform self-management when traditional self-monitoring of blood glucose has been insufficient
- Requires evidence of glycaemic control, e.g. for the DVLA
- Motivated to improve glycaemic control or to adjust insulin to meet their lifestyle needs

Local application

About 18 months ago the opportunity to use a CGM device within out local diabetes centre arose. The CGM device was loaned to the centre at Broomfield Hospital, Chelmsford, by the manufacturer. The initial period of loan was set at 6 months, but because we have used the device fairly extensively, the loan has been extended, and so far 30 people with diabetes have worn the device.

Participants

Twenty nine of the 30 people who have worn the device have type 1 diabetes and are using a multiple injection regimen. People with type 2 diabetes were not excluded as long as they met all the criteria stated in *Table 1*. Participants

were selected on the basis that conventional capillary blood glucose monitoring had failed to support appropriate diabetes treatment changes. The age range and gender split of people who have worn the device are shown in *Figure 1*.

Process

Participants wore the device for a 48-hour period and were asked to keep a diary of their activities, including timing and dosage of insulin, dietary intake, and activity – work-based or otherwise. In addition, they were asked to complete a product evaluation form and 20 of the 30 participants did so.

Participants were required to visit the diabetes centre for insertion of the device and then again 2 days later for removal. A third visit was then arranged with a diabetes specialist nurse to discuss the results.

Consent

Once the person had agreed to wear the device, consent was obtained following explanation of the procedure for insertion of the microfibre. Participants were advised at this stage that insertion of the introductory needle and cannula could be uncomfortable. Some participants chose to apply Emla cream (lidocaine 2.5%, prilocaine 2.5%; AstraZeneca, Luton) under an occlusive dressing about an hour before the procedure.

The trust's consent form 'Treatment and investigation where consciousness is not impaired' was utilised as a framework for consent and as a documentation tool.

Findings

The majority of comments made by participants relate to the wearing of the device and are summarised in *Table 2*. The benefits of wearing the device from the person with diabetes' perspective are summarised in *Table 3*. There were no major drawbacks from other than those outlined in *Table 2*. Feedback was gained via a short questionnaire which asked participants to describe their experiences of wearing the device and whether wearing the device changed the way they managed their diabetes. The benefits of the system from the healthcare professional's perspective are outlined in *Table 4*. The comments were drawn from the diabetes specialist nurses (DSNs) that fitted the device to the study participants. The DSNs were informally asked to outline the benefits of the system they perceived for the person wearing the device and what changes had been made to each person's management plan.

Table 2. Comments made by people wearing the device.

- Device is bulky and Velcro strap itchy
- The clock is difficult to read
- Partners of some participants commented about the noise at night-time
- Not being able to have a shower/bath was a problem for some people
- Uncomfortable when sitting/driving; difficult to position
- Not uncomfortable at all

Table 3. Perceived benefits: the perspective of the person with diabetes.

- Detection of unrecognised hypoglycaemia and confidence building around this
- Confidence to self-adjust more effectively
- Better understanding of the impact of diet and exercise on glucose levels
- Provides reassurance about nocturnal hypoglycaemia
- Identification of what to avoid, e.g. appropriate timing of insulin

Table 4. Perceived benefits: the health professional's perspective.

- Provides evidence of undetected hypoglycaemia
- Opportunity to re-educate, especially in relation to insulin adjustment
- Dispels diabetes misconceptions
- Provides evidence to support clinical decisions
- Provides reassurance

Limitations

As already stated, CGM has been tried and tested in those people for whom conventional means have failed to improve glycaemic control. On a cautionary note, in each case it is important to have clear objectives at the outset of CGM. For example, is undetected hypoglycaemia suspected? Is there a doubt about the duration of action of a person's basal insulin? In our experience, it is not appropriate to fit the device to every person who has a less than desirable HbA_{1c} level. Selection criteria were written to achieve this aim.

Page points

1. The authors have found the device useful in helping some people to manage their diabetes more effectively.
2. Some participants changed their insulin regimens and one was able to prove to the DVLA that her driving licence should be returned to her.

Page points

1. The continuous glucose monitoring (CGM) system is not suitable for all people with diabetes, but the majority of people who have used it have made changes to the way they manage their diabetes.
2. The author would like to expand the service offered by her team, but will need to build it into the business planning process next year.
3. If the bid were successful, the service could be offered to primary care colleagues.
4. CGM fits in well with insulin pump therapy and would support the development of such a service in the near future.

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Time is a major limiting factor when providing a CGM service. In order to obtain the person with diabetes' informed consent and set up the device, 45 minutes to 1 hour must be set aside, or longer if he or she wishes to use the Emla cream. It takes only a few minutes to take the device off, and around 30 minutes to download the information and clean the machine. Finally, the person requires a one-to-one consultation with the diabetes nurse to discuss the results and agree an action plan. Given our current resources, we can only offer one slot per week for this process, or one slot per fortnight when a DSN is on holiday.

It should be noted that this is not a research study, but rather an evaluation of a product that has been around for some time. The information presented is of an anecdotal nature and is intended to give an overview of its application to practice at local level.

Conclusions and future plans

Although this technology has been around for some time, we have found it useful in helping some people to manage their diabetes more effectively. It is not suitable for all people with diabetes, but the majority of people who have used it have made changes to the way they manage their diabetes. Some have changed their insulin regimens and one person was able to prove to the DVLA that her driving licence should be returned to her. We would hope be able to compare pre- and post-device HbA_{1c} in around 6 months' time to ascertain whether or not there has been an improvement as a result of the changes made to the patients' insulin regimen or lifestyle.

We have already mentioned the patient diaries that support the graphs and tables generated by the device. This tool has been particularly useful in gaining an insight into the participant's lifestyle, as in our experience participants were extremely honest when completing them, especially in terms of perceived dietary indiscretions and timing of insulin.

We would like to expand the current level of service, but will have to build this into the business planning process for next year – so far, we have been provided with patient disposable sets free of charge, but we cannot expect this arrangement to continue in the long term. If a bid is successful, we would be in a position to offer this service to our primary care colleagues.

Our dietitian has arranged for the whole diabetes team to learn carbohydrate counting next year, and CGM could link with this educational process. In the longer term, CGM could fit in well with insulin pump therapy and would support the development of such a service in the near future. ■

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