7 Geffner ME, Lippe BM, Maclaren NK, Riley WJ. Role of autoimmunity in insulinopenia and carbohydrate derangements with cystic fibrosis. *J Pediatr* 1988; **112** (3): 419–21.
8 De Luca F, Arrigo T, Conti Nibali S *et al*. Insulin secretion, glycosylated haemoglobin and islet cell antibodies in cystic fibrosis children and adolescents with different degrees of glucose tolerance. *Horm Metab Res* 1991; **23** (10): 495–8.
9 Lanng S, Thorsteinsson B, Pociot F *et al*. Diabetes mellitus in cystic fibrosis: genetic and immunological markers. *Acta Paediatr* 1993; **82** (2): 150–4.
10 Moran A, Hardin D, Rodman D *et al*. Diagnosis, screening and management of cystic fibrosis related diabetes mellitus: a consensus conference report. *Diabetes Res Clin Pract* 1999; **45** (1): 61–73.
11 Lanng S, Hansen A, Thorsteinsson B, Nerup J, Koch C. Glucose tolerance in cystic fibrosis: a five year prospective study. *BMJ* 1995; **311** (7006): 655–9.

# Talking glucose meter for the visually impaired diabetic patient: the effect of haematocrit on glucose measurement

R. W. A. PEAKE*, M. S. DEVGUN* and I. A. D. O'BRIEN†
*Departments of *Biochemistry and †Medicine, Wishaw General Hospital, Lanarkshire ML2 ODP, UK*

Diabetic retinal disease is a major complication of diabetes and has an incidence of 50–65 per 100,000 in the diabetic population per year in Europe.[1] Anaemia is also a common complication of diabetes mellitus (DM), associated with diabetic nephropathy and chronic kidney disease, resulting in the failure of erythropoietin production.

Among the 29 glucose systems considered in a recent review,[2] only one is listed to have an acoustic mode facility. In recent years, however, attempts have been made to address this problem with the introduction of 'talking' blood glucose monitors, particularly in the USA. In contrast, the UK market contains few options for meters featuring speech output. In the UK, the SCP Talking Meter (BBI Healthcare)[3] became available in April 2006 for use by the visually impaired diabetic patient.

This study describes a 30-year-old male with type 1 DM diagnosed at the age of six. Owing to the occurrence of repeated hypoglycaemic episodes and poor compliance with insulin therapy and diet (body mass index [BMI]: 18) he was issued with an SCP meter. His average glycated haemoglobin (HbA1c) level was approximately 15% (4.8–6.7%), equivalent to 140 mmol/mol (20–42 mmol/mol) on the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) standardised method. He had peripheral neuropathy, significant diabetic nephropathy and developed retinopathy, which progressively limited his vision. On the Snellen scale, his initial visual acuity was 6/60 but seven months later this had deteriorated such that he was only able to count the number of fingers held up in front of him. He was anaemic (Hb: 8–9 g/dL, haematocrit [Hct] 26–28%) and his medication included 200 mg ferrous sulphate (three times a day).

*Correspondence to: Dr. M. S. Devgun*
*Clinical Laboratories, Department of Biochemistry, Wishaw General Hospital, 50 Netherton Street, Wishaw, Lanarkshire ML2 ODP, UK*
*Email: manjit.devgun@lanarkshire.scot.nhs.uk*

**Table 1.** SensoCard Plus (SCP) and Accu-Check Advantage (ACA) meter: glucose measurements at haematocrit 46% Hb.

| Expected (mmol/L) | SCP (mmol/L) | ACA (mmol/L) | SCP minus expected (%) | ACA minus expected (%) |
|---|---|---|---|---|
| 2.5 | 5.1 | 5.7 | 104.0 | 128.0 |
| 5.0 | 7.0 | 8.5 | 40.0 | 70.0 |
| 7.5 | 8.2 | 9.5 | 9.3 | 26.7 |
| 10.0 | 10.5 | 11.5 | 5.0 | 15.0 |
| 12.5 | 12.0 | 13.2 | –4.0 | 5.6 |
| 15.0 | 15.0 | 16.5 | 0.0 | 10.0 |
| 17.5 | 17.3 | 19.2 | –1.1 | 9.7 |
| 20.0 | 20.4 | 22.1 | 2.0 | 10.5 |

The patient provided Informed consent for this study, which is written following the guidelines issued by the area ethical committee.

In the diabetic clinic the patient's whole-blood glucose was measured by a trained laboratory scientist using the issued SCP meter, and a glucose of 25.8 mmol/L was obtained with acceptable internal quality control performance using the laboratory's standard operating procedure. The same specimen was checked using a ward-based glucose meter (Accu-Check Advantage [ACA], Roche) using a glucose dehydrogenase and coenzyme paraquinone quinoline assay (coefficient of variation [CV] <3.5%), and a glucose of 13.0 mmol/L was observed. This discrepancy was confirmed on a venous sample using the laboratory's routine method (13.2 mmol/L, glucose oxidase assay, CV <2%).

The performance of the patient's SCP meter was assessed by investigating its linearity over a range of glucose and Hct concentrations. First, serial dilutions ($n$=8, in duplicate) of a patient's whole blood specimen at constant Hct (46%) were spiked with a 0.5 mol/L glucose solution to generate a range of approximately 2.5–20 mmol/L (well within the recommended concentration range for both meters).

The means of the duplicate glucose readings obtained from the SCP and ACA meters were compared using a paired $t$-test ($t$=9.22, $P$<0.0001). Data points from the SCP meter were similar to the expected glucose values; all observations from the ACA meter were positively biased (Table 1). In addition, the ACA results were higher than those obtained with the SCP meter (mean difference: 10.2 %) within the glucose range 10–20 mmol/L.

Overall, acceptable and comparable linearity over the specified range was observed on both machines. Results became increasingly inaccurate when plasma glucose was ≤5.0 mmol/L, with both meters giving higher figures than the values obtained using the laboratory method. This study confirmed the correct functioning of the patient's SCP meter.

The SCP and ACA meters were also tested over a range of Hct values (Table 2). A whole-blood sample was diluted ($n$=9, in duplicate) in a plasma-based matrix to achieve Hct in the range 19–47% (laboratory reference ranges: males 40–54%, females 37–47%). The observations demonstrated a

**Table 2.** SensoCard Plus (SCP) and Accu-Check Advantage (ACA) meter: glucose (mmol/L) and haematocrit (Hct) measurements.

| Hct (%Hb) | GLU expected | SCP GLU | ACA GLU | SCP– expected (%) | ACA– expected (%) |
|---|---|---|---|---|---|
| 19 | 7.5 | 12.1 | 8.6 | 61.3 | 14.7 |
| 23 | 10.0 | 14.6 | 10.6 | 46.0 | 6.0 |
| 28 | 12.5 | 15.7 | 13.0 | 25.6 | 4.0 |
| 33 | 15.0 | 19.4 | 15.6 | 29.3 | 4.0 |
| 37 | 17.5 | 20.2 | 17.3 | 15.4 | –1.1 |
| 42 | 20.0 | 21.7 | 19.9 | 8.5 | –0.5 |
| 47 | 25.0 | 23.0 | 22.1 | –8.0 | –11.6 |

significant difference ($t$=3.1, $P$<0.02) between the two meters. Over-estimation of glucose concentration by the SCP meter at Hct <37% was apparent. At Hct ≤ 33%, the SCP meter glucose values were on average 33.4% higher than those obtained using the ACA meter; Batki and coworkers[2,3] reported variations of 10–20%.

The observed glucose bias by the SCP meter (Table 2) was lower than that seen in the diabetic subject, and this may arise due to the different specimen matrix used in the course of the experiments. *In vitro* study cannot fully replicate the effect of components present in the patient's blood (i.e., cellular components, plasma constituents and the continued consumption of glucose). Samples with low Hct will have proportionately higher diluent volume, and therefore the observed glucose bias (Table 2) will be lower than that demonstrated in the patient's blood.

In the UK, the SCP glucose meter is the system of choice for visually impaired patients with diabetes. It has received approval from the Centre for Evidence-based Purchasing (CEP) of the NHS Purchasing and Supplying Agency (PASA) in cooperation with the Medicines and Healthcare products Regulatory Agency (MHRA).[3]

The SCP meter utilises a glucose oxidase method and is recommended for use with capillary blood samples between the Hct range 30–55%. The CEP report[3] confirmed that the meter performed satisfactorily across this range and varied considerably in reporting glucose concentrations at Hct levels <30%, in keeping with the manufacturer's specifications. In contrast, the authors found significantly increased glucose readings at Hct levels ≤37%.

The MHRA reviewed[2] 13 types of meter, all of which were capable of measuring glucose within the 1 mmol/L to 22–33 mmol/L range, although measurements below the lower reference range are unlikely to be accurate. The CEP report[2] indicates that some point-of-care (POC) meters are designed to eliminate interference arising from variable Hct levels. In five meters studied by the MHRA, the manufacturers' specified lower Hct limit was 20%; in a further two the lower limit was 25%. Therefore, all would appear to be fit for purpose in the secondary care environment, although none had acoustic facility/function.

In contrast, in 11 meters evaluated for the primary care sector and for home monitoring use, the lower glucose limit quoted is approximately 1 mmol/L, with an upper limit of 27.8–33.3 mmol/L. Only four meters are capable of measuring glucose with Hct at approximately 20%. In one, the lower limit for Hct is 25% and the remaining six are suitable for use when Hct is ≥30%.

In the authors' laboratory audit of 4459 diabetic subjects (2135 males, 2324 females) Hct was found to be <37% in 997 specimens (22.2 %). Furthermore, Hct of <30% was present in 111 samples (2.5 %), representing 1.5% male and 3.4% female patients with DM.

Overall prevalence of Hct <37% in the authors' hospital is 43.5 % ($n$=15,235) and <30% is 14.6%. In those with serum glucose >11 mmol/L, the prevalence is 8.6%. These figures are similar to those reported for type 2 DM with end-stage renal disease[4] and in other renal patients.[5]

It has been shown previously that the quality of glucose measurement depends on factors such as poor user technique and/or variations in glucose test-strip accuracy.[6] From the present study, it is evident that when such factors have been excluded as a possible cause, poor quality can be due to glucose meter capability (specification) at low Hct, as seen in the case study presented here. Therefore, when issuing a glucose meter for home monitoring, Hct capability must always be addressed. Of the five visually impaired diabetic subjects in the district, four have an Hct within the specification range of the SCP 'talking' meter (Hct: 30–55%). In these subjects, the Hct strongly correlated ($r$=0.96) with the Hb value (Hct=3.3+2.76 Hb). Therefore, in those patients with an Hb <11 g/dL it is likely that some Hct-associated discrepancy in glucose measurement will occur when using the SCP meter.

Local guidelines promote the use of the SCP meter and currently no alternative is available with acoustic facilities. The situation is further complicated by the fact that no other 'talking' meters are approved by MHRA for use in the UK. Availability of the SCP meter is a technological advance in monitoring glycaemia in the visually impaired subject; however, the present findings indicate that it is unsuitable for some anaemic patients because of the specific Hct range within which it may operate. □

## References


1 Trautner C, Icks A, Haastert B, Plum F, Berger M. Incidence of blindness in relation to diabetes. A population-based study. *Diabetes Care* 1997; **20** (7): 1147–53.

2 Batki AD, Nayyar P, Thomason H, Thorpe GH. NHS Purchasing and Supply Agency, Centre for Evidence-based Purchasing, Report 08008, Buyers' guide: Blood glucose systems. May 2008.

3 Batki AD, Nayyar P, Thomason H, Holder R, Thorpe GH. NHS Purchasing and Supply Agency, Centre for Evidence-based Purchasing, Report 05088. CDX SensoCard Plus talking blood glucose system. October 2005:; 1–32.

4 Yang XL, So Y, Kong AP *et al*. End-stage renal disease risk equations for Hong Kong Chinese patients with type 2 diabetes: Hong Kong Diabetes Registry. *Diabetologia* 2006, **49** (10): 2299–308.

5 Nikolsky E, Mehran R, Lasic Z *et al.* Low hematocrit predicts contrast-induced nephropathy after percutaneous coronary interventions. *Kidney Int* 2005; **67** (2): 706–13.

6 Kirk J, Kilpatrick ES. Do some blood glucose meters really read differently to others? *Practical Diabetes International* 2000; **17** (1): 13–4.