How accurate are blood glucose meters used for patient self testing?

M O'Kane[1,2], M. McCloskey[1], Celia Diver-Hall [1,2]

[1]Clinical Translational Research and Innovation Centre (C-TRIC), [2]Diabetes Clinic, Altnagelvin Hospital, Londonderry, BT47 6SB, Northern Ireland

INTRODUCTION

There is increasing concern about the accuracy of glucose meters used for monitoring and managing glycaemic control in hospitalised patients. A number of endogenous and exogenous substances can influence the accuracy of results and as such several bodies [ISO, IFCC, FDA] are looking at revised performance criteria for hospital glucose meter performance. Since diabetes patients rely on self monitoring of blood glucose [SMBG] meters to identify hyper- and hypoglycaemia and modify treatment accordingly, it is also important for patient glucose meter readings to be accurate and reliable in order to reduce the risk of inappropriate management. However it has been reported by the ADA that up to 50% of all SMBG readings may vary from their true value by more than 20% raising a question mark over their reliability.

AIM OF THE STUDY

The purpose of this study was to;
1. Challenge the design and analytical performance of commonly used SMBG meters in order to assess the impact of recognised interfering factors
2. To assess the accuracy of the best and worst performing SMBG meters identified in part 1 above when used to measure glucose in a diabetic patient population.

METHODS

Analytical Evaluation
Meters Assessed
1. NovaMax plus [Nova Biomedical]
2. Glucofix Mio plus. [Menarini Diagnostics]
3. Glucomen Lx plus [Menarini Diagnostics]
4. AccuCheck Aviva [Roche Diagnostics]
5. Ascencia Breeze 2 [Bayer Heatlh Care]
6. Optium Xceed [Abbott Diagnostics]
7. OneTouch Ultra [LifeScan]

METHODS [Continued]

Reference Methods
1. YSI 2300 [Yellow Springs]
2. Hexokinase /G6PD [Abbott Architect]

Precision
The imprecision (expressed as coefficient of variation [CV] of each meter was determined at three different concentrations and this was used in conjunction with the bias deviation to calculate mean Total Error [%bias + 1.65 CV(%)].

Method Correlation
A method correlation was performed using a spiked sample panel prepared from a donated whole blood..

Interferences
The meters were challenged with differing haematocrit [Hct] levels and differing concentrations of non-glucose sugars (maltose, galactose, xylose) and at five different glucose concentrations (1.1-3.3, 5.5-8.3, 11.1-16.7, 18.1 – 22.2 and 23.6-27.8 mmol/L). Each individual sample was tested 6 times with each meter.

Patient Evaluation
Meters Assessed
1. Nova Max plus [Nova Biomedical]
2. OneTouch Ultra [LifeScan]

Reference Methods
1. YSI 2300 [Yellow Springs]

Sample Collection:
Glucose testing was performed on 130 patients attending outpatient diabetes clinics. Capillary blood (200ul) and was tested using the SMBG meters and YSI 2300 and for each patient the whole blood haematocrit level was determined

RESULTS

Analytical Evaluation
Precision
Most of the meters demonstrated good within day and between day imprecision with CV's <7% for the low concentration [~ 2.5mmol/L] glucose samples and <5% for the medium [~10.5mmol/L] and high [20mmol/L] concentration glucose samples. The imprecision for Ascencia Breeze, Optrium Xceed and One Touch Ultra meters was slightly poorer for the low and medium concentration samples

Method Correlation and Total Error
Linear regression analysis showed a good correlation of all the meters to the hexokinase reference method [r[2]. > 0.996]. Total Error varied between meters and was least for Glucomen LX Plus and greatest for One Touch Ultra [Table 1].

Interferences
AccuChek Aviva, Ascencia Breeze, Optimum Xceed and One Touch Ultra were affected by Hct; other meters were unaffected [Table 1]. The Nova Max plus, Glucofix mio and Glucomen Lx were unaffected by the interference from maltose, galactose and xylose[Table 1]. The other meters were affected to varying degrees. The Nova Max plus and One Touch Ultra were selected for diabetic patient testing.

Table 1

Meter	Total Error	Hct (22%)	HCT (62%)	Maltose (5.6 mmol/L)	Galactose (5.6 mmol/L)	Xylose (5.6 mmol/L)
NovaMax plus	8.5%	9.3%	5.8%	6.8%	6.7%	7.8%
Glucofix mio Plus	7.8%	3.8%	5.8%	11.5%	9.1%	6.4%
Glucomen Lx Plus	7.2%	7.1%	4.1%	8.3%	10.4%	4.7%
AccuChek Aviva	9.5%	20.2%	13.4%	20.2%	68.0%	15.4%
Ascencia Breeze 2	9.5%	31.6%	32.7%	19.8%	13.0%	9.3%
Optium Xceed	15.5%	35.2%	41.7%	14.7%	11.5%	13.6%
One Touch Ultra	16.6%	31.9%	47.0%	17.0%	21.9%	16.3%

RESULTS [Continued]

Patient Evaluation.
Conformance to ISO 15197

	Within 0.28 mmol/L	Within 0.56 mmol/L	Within 0.83 mmol/L
ISO Target	45%	70%	95%
NovaMax Actual %	50%	71.4%	100%
One Touch Ultra Actual %	50%	71.4%	100%

	Within 5%	Within10%	Within 15 %	Within 20 %
ISO Target	22%	49%	85%	95%
NovaMax Actual %	41.1%	72.6%	91.9%	96.8%
One Touch Ultra Actual %	37.9%	69.4%	85,5%	93.6%

Haematocrit Interference
One Touch Ultra was affected by Hct with results increased at lower Hct and reduced at higher Hct. The Novomax Plus was unaffected by Hct .
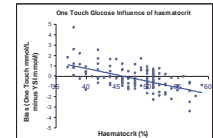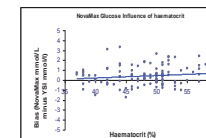
CONCLUSIONS

The accuracy of SMBG meters can be affected by haematocrit as well as non-glucose sugars. Haematocrit interference was confirmed in real patient samples. Inaccurate SMBG results increase the risk of inappropriate management of diabetes and new performance criteria for SMBG meters should take this into account.