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## **Precision and Accuracy of Three Blood Glucose Meters: Accu-Chek Advantage, One Touch Horizon and Sensocard**

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This study evaluated the accuracy and precision associated with the use of three popular alternative-site blood glucose monitors, Accu-chek Advantage, Onetouch Horizon and Sensocard, using forearm venous blood samples and capillary blood samples. The study was conducted from January to March, 2009 at the Komfo Anokye Teaching Hospital, Kumasi. One hundred and ninety consenting subjects were included in the study. The blood glucose levels were analyzed on glucose meters; Accu-chek Advantage, Sensocard and Onetouch Horizon by finger stick, using amperometry Technology. At the same time venous blood glucose was analyzed using the WHO reference Glucose Oxidase Method (GOD). The mean value generated by the WHO reference method ( $7.91 \pm 0.35$ ) was not significantly different ( $p = 0.2816$ ) from that produced by the Accu-chek Advantage ( $8.46 \pm 0.36$ ), Sensocard ( $7.72 \pm 0.35$ ;  $p = 0.7028$ ) and Onetouch Horizon ( $7.97 \pm 0.35$ ;  $p = 0.9044$ ). Bland-Altman analysis indicates that Onetouch Horizon and Accu-chek Advantage have the tendency of overestimating blood glucose with a bias of -0.1 and -0.5, respectively. Sensocard could under-estimate with a bias of 0.2. In terms of rating, while all the glucose meters gave precisions at about the same level (i.e., 1.0), Onetouch Horizon is generating the closest value to the reference method with a difference between mean of -0.06, followed by Sensocard of 0.19 and Accu-chek Advantage with a value of -0.55. The precision of the Accu-chek Advantage, Onetouch Horizon and Sensocard for blood glucose monitoring from about 3.1-33.3 mmol L<sup>-1</sup> is good. However, the Accu-chek Advantage has the tendency to overestimate at the hypoglycaemic levels. The Accu-chek Advantage is capable of estimating both capillary and venous blood glucose to the same level of accuracy. The Onetouch Horizon and Sensocard are however incapable of efficiently estimating venous blood glucose.

**Key words:** Diabetes, glucose meters, glucose oxidase method, accuracy, precision

## INTRODUCTION

Self-monitoring of blood glucose is an important tool for assessing glycaemic conditions in patients presenting with diabetes mellitus. It has been established that the progression of all major complications associated with this disease could be suppressed if patients were held in tighter glycemic control (ADA, 2002). Recent studies have indicated that outcomes in critically ill patients are improved when blood glucose levels are maintained in a euglycemic range (Bochicchio *et al.*, 2005; Krinsley, 2003; Van-den-Berghe *et al.*, 2001).

Furthermore, changes in medical practice have intensified institutional pressures to achieve clinical efficacy. Thus, hospitals are decreasing the admission of patients with non-acute conditions and increasing the proportion of patients admitted for major therapeutic interventions (Jacobs *et al.*, 1993; Welschen *et al.*, 2005). One of the mechanisms used to meet these clinical needs is the use of point of care testing (Friedman and Mitchell, 1993). Point-of-care testing or near patient testing is defined as Diagnostic Testing that is performed near or at the site of patient care (Jacobs *et al.*, 1993; Thomas *et al.*, 2008). Major advantages of near patient testing are the time saving that could facilitate important diagnostic and management decisions (Nanji *et al.*, 1988; Welschen *et al.*, 2005).

Most of the benefits for the physicians, nurses, patients and medical administrators are based on the belief that faster is better and that more rapid testing at bedside will improve medical care and decrease utilization of hospital resources (Jacobs *et al.*, 1993). The dynamic equilibrium between medical utility, technological capabilities and cost determines whether laboratory testing is conducted in central laboratories or at distributed sites (Winkelman *et al.*, 1994).

Accuracy is the ability of a test to produce results close to the best available measure (Dillon *et al.*, 1997). Glucose meters may not be very accurate across the full range of glucose values, especially lower values, its utility however, as a screening tool can not be underestimated (Hamid *et al.*, 2004). Point of care testing is not widely used in hospitals; there are only few places like intensive care units and emergency departments where glucose testing is performed to know the current status and to provide immediate care to the patient. In various hospitals and out patient clinics, glucose meters are widely used as a first line tool to get an idea about the current blood glucose levels. Recent advances in technology have made available a number of systems that allow near-patient testing. Results are produced within minutes which compare favourably to the much longer time experienced with centralized testing.

Available data has also confirmed that majority of patients presenting with diabetes do not perform Self-Monitoring of Blood Glucose (SMBG) (ADA, 2002; Harris *et al.*, 1993; Saudek *et al.*, 2006). One reason is the physical and psychological discomfort associated with the traditional finger-stick method of blood sampling (ADA, 2002; McGarraugh *et al.*, 2001). Until recently, the finger-stick method was the only accurate method for patients using SMBG; however, glucose monitoring devices that use blood from other sites are now available (Thomas *et al.*, 2008; Rivers *et al.*, 2006). These monitors offer patients the choice of using either the traditional finger-stick method or using an alternative site, such as the forearms, palms, or thighs, thereby reducing pain (McGarraugh *et al.*, 2001). To date, no direct comparisons of alternative-site blood glucose testing meters have been published in the Ghanaian setting.

Regardless of the fact that the accuracy and precision of a number of SMBG have been evaluated in the past (Thomas *et al.*, 2008; Rivers *et al.*, 2006; Devreese and Leroux-Roels, 1993) a number of new SMBG machines, which utilise non-wipe methods, have been developed in recent years. Some of these machines are yet to be subjected to vigorous assessment by an independent body despite their popularity.

Apart from this, in routine clinical practice, cases of mismatch between glucose meter values of blood sugar and clinical signs and symptoms have been encountered and this has raised anxiety and concern among patients and clinicians. To gain insight into this issue, the primary purpose of our study was to evaluate the accuracy and precision associated with the use of three popular alternative-site blood glucose monitors, Accu-chek Advantage, Onetouch Horizon and Sensocard, using forearm venous blood samples and capillary blood samples.

## MATERIALS AND METHODS

**Subjects:** This study was conducted between January and March, 2009. The subjects of this study were recruited from an adult population in Kumasi, Ashanti region, Ghana. A total of 190 subjects were recruited; 100 subjects from the diabetic clinic and 50 non-diabetic subjects at the Komfo Anokye Teaching Hospital, Kumasi, Ghana were recruited for the purpose of assessing the accuracy of the three blood glucose meters and for comparing methods. Another 40 subjects were also recruited from the same site for the purpose of comparing the performance of each blood glucose meters using venipuncture and fingerstick capillary blood samples. After explanation of the study's purpose and

testing procedure, patient demographic information which include: age, sex and absence or presence of diabetes was documented. Exclusion criteria from this study include pregnant women, children under 18 years of age and subjects who were on medication that could interfere with plasma glucose. Informed consent was obtained from all patients. The study was approved by the local Committee on Human Research Publication and Ethics (Chrpe/Knust/Kath/03-03-09).

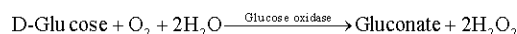
The blood glucose level of the venipuncture samples of the 150 subjects (100 diabetics and 50 non-diabetics subjects) were determined using the laboratory WHO recommended manual glucose oxidase method (Trinder, 1969) whereas the blood glucose level of the capillary samples from these same subjects were determined using each blood glucose meter. Using the same arm, duplicate finger and venipuncture glucose measurements were taken from the other (40) subjects. Blood samples from the same subject were used for each set of duplicate tests. The finger and venipuncture samples were run on each glucose meter while only the venipuncture samples were dispensed into fluoride oxalate tubes, centrifuged at 500 g for 5 min and analyzed by the manual glucose oxidase method (Trinder, 1969).

**Sample collection and preparation:** Blood samples were collected from the ante cubital vein after an overnight fast (12-16 h). A tourniquet was applied for less than one minute and the site to be punctured cleaned with 70% methylated spirit. Two milliliter of blood was dispensed into fluoride-oxalate tube. At the same time, capillary blood samples were taken with three different glucose meters namely Sensocard (CDx Ltd, Stanfield Business Centre, Sunderland, UK), Onetouch Horizon (LifeScan Inc., Milpitas, CA, USA) and Accu-chek Advantage (Roche Diagnostics Division, Grenzachstrasse, Switzerland) and glucose values obtained recorded. The determination of meter sequence was randomly assigned. Test strips with identical lot numbers (Accu-chek, Lot 2030381, Sensocard Lot FT01EA88C and One Touch Horizon Lot 2838983) were used for the study.

Results of finger and forearm glucose measurements were compared with the laboratory reference value obtained via venipuncture. One investigator performed all measurements in accordance with the manufacturers' instructions. The fluoride containing blood was then taken to the laboratory and centrifuged at 500 g for 5 min to obtain the plasma. The plasma samples were analyzed manually with a spectrophotometer (Spectomic Genesystem 20, USA) making use of glucose oxidase test kit (Fortress, Antrim, United Kingdom) to measure the concentration of glucose of patients. The glucose determination was done according to the method described by Trinder (1969).

#### **Principle of the WHO reference glucose oxidase method:**

Glucose levels were determined by a commercially available enzymatic spectrophotometric glucose oxidase method (Fortress, Antrim, United Kingdom). The basic principle is that, glucose oxidase specifically converts glucose to gluconate and hydrogen peroxide.



Subsequently, there is a reaction between  $\text{H}_2\text{O}_2$  and a peroxidase-dye indicator 4-aminophenazone and phenol under the catalysis of the second enzyme peroxidase (POD) to yield a red-violet quinoneimine dye as the oxidized dye:



The absorbance of which is measured at 500 nm with a spectrophotometer (Spectomic Genesystem 20, USA). The amount of colored end product is proportional to the amount of glucose present in the sample (Goldstein *et al.*, 2004). According to the manufacturer, the test is linear up to  $27.8 \text{ mmol L}^{-1}$  ( $1500 \text{ mg dL}^{-1}$ ). Samples above this concentration should be diluted 1:2 with distilled water, reassayed and the result multiplied by 3. This method will accurately measure glucose levels down to  $0.35 \text{ mmol L}^{-1}$  ( $6.3 \text{ mg dL}^{-1}$ ). The glucose concentration is then calculated as follows:

$$\text{Glucose (mmol L}^{-1}\text{)} = \frac{\text{Absorbance of test}}{\text{Absorbance of standard}} \times \text{Concentration of standard}$$

A reference curve was constructed of known glucose concentration for the calibration and to determine the linearity of the kit for the spectrophotometer used. The results of the glucose concentration obtained using the WHO approved glucose oxidase method was used as the target value i.e., the best result the reference laboratory could obtain for the analyte in that sample.

#### **Principle of the Accu-chek advantage:**

Glucose dehydrogenase in the strip converts the glucose in the blood sample to gluconolactone. This reaction liberates two electrons that react with a coenzyme (PQQ) electron acceptor. The complete reaction creates a harmless electrical current that the meter interprets as blood glucose. According to the manufacturer, the test is linear up to  $33.3 \text{ mmol L}^{-1}$  ( $600 \text{ mg dL}^{-1}$ ). This method will accurately measure glucose levels down to  $0.6 \text{ mmol L}^{-1}$  ( $10 \text{ mg dL}^{-1}$ ).

**Principle of the Onetouch Horizon:** Glucose in the blood sample mixes with special chemicals on the test strip and a small electrical current is produced. This current is

measured by the OneTouch Horizon meter and displayed as blood glucose result. The strength of these currents changes with the amount of glucose in the blood sample. According to the manufacturer, the test is linear up to 33.3 mmol L<sup>-1</sup> (600 mg dL<sup>-1</sup>). This method will accurately measure glucose levels down to 1.1 mmol L<sup>-1</sup> (20 mg dL<sup>-1</sup>).

**Principle of the Senso Card:** The SensoCard analysis applies the enzyme glucose oxidase and is based on advanced electromechanical technology that is specific for beta-D-glucose measurement. Test strips are designed such that the blood sample absorbs into the reaction zone, after blood has been applied to the tip of test strip. In the reagent zone, glucose oxidase triggers the oxidation of glucose in blood. Intensity of formed electrons is measured by the meter and correlates well with the concentration of glucose in the blood sample. According to the manufacturer, the test is linear up to 33.3 mmol L<sup>-1</sup> (600 mg dL<sup>-1</sup>). This method will accurately measure glucose levels down to 1.1 mmol L<sup>-1</sup> (20 mg dL<sup>-1</sup>).

**Statistical analysis:** Statistical analysis was performed using MedCalc Version 10.2.0.0 for windows 98/NT/Me/2000/XP/Vista (Vienna, Austria. <http://www.medcalc.be>). The Bland-Altman analysis was used to compare the reference WHO manual glucose oxidase method with the other glucose meters (Bland and Altman, 1986; Altman and Bland, 1986). An unpaired t-test and Fischer exact test were used to compare the glucose concentrations among the various groups and category of subjects with a p value of less than 0.05 accepted as statistically significant.

## RESULTS

As shown in Table 1 from this study, the minimum fasting blood sugar generated by the reference WHO manual glucose oxidase (God) method was 3.1 mmol L<sup>-1</sup> while that of the glucose meter Accu-chek (Fig. 4b) was 4.0 mmol L<sup>-1</sup>, Sensocard was 3.9 mmol L<sup>-1</sup> and Onetouch

was 3.8 mmol L<sup>-1</sup>. The maximum value generated was 28.6, 32.2, 27.6 and 28.2 mmol L<sup>-1</sup> for the reference God, Accu-chek, Sensocard and Onetouch, respectively. When the mean value of the reference God was compared to the various glucose meters using an unpaired t-test, there was no significant difference with respect to each of the glucose meters as shown by the p-value. However, the negative difference between mean values of Accu-chek and Onetouch means that, they were generating values higher than that of the reference manual God (Table 1). Sensocard however, is generating values much lower than that of the reference manual glucose oxidase method. The bias (mean difference scores between glucose meter and laboratory reference values) and precision (standard deviation of the mean difference scores) for Accu-chek is -0.5455 and 1.042, respectively, for Sensocard is 0.1882 and 0.9529, respectively and for Onetouch is -0.0598 and 1.312, respectively.

Among the 150 subjects, 44 (29.3%) had differences of 1.0 mmol L<sup>-1</sup> or greater between the laboratory reference glucose values and Accu-chek, 46 (30.7%) had differences of 1.0 mmol L<sup>-1</sup> or greater between the laboratory reference glucose values and Onetouch and 37 (24.7%) had differences of 1.0 mmol L<sup>-1</sup> or greater between the laboratory reference glucose values and Sensocard. Considering the Mean±SEM for each glucose meter and GOD, Onetouch Horizon gave a mean difference of 7.97, Sensocard 7.72 and Accu-chek Advantage 8.46 as compared to God value of 7.91 (Table 1). Even though they were not significantly different, it is obvious that the Onetouch Horizon generated values which were close to that of God, an observation which is evident from the minimum and maximum values shown in Table 1.

From the Bland-Altman analysis in Fig. 1, when the WHO reference manual God was compared to the Accu-chek glucose meter, it indicated that the Accu-chek was generating glucose results higher than that of the reference method. This is in line with the earlier observation in Table 1. The bias from this is -0.5 and the 95% limit of agreement are -2.6 to 1.5 (Fig. 1a). In this

Table 1: General characteristics of the various methods

| Parameters               | God        | Accu-check | Sensocard  | Onetouch   |
|--------------------------|------------|------------|------------|------------|
| Minimum                  | 3.100      | 4.00       | 3.90       | 3.80       |
| 25% Percentile           | 5.060      | 5.60       | 5.00       | 4.90       |
| Median                   | 6.280      | 6.50       | 5.90       | 6.15       |
| 75% Percentile           | 9.868      | 10.13      | 9.05       | 9.80       |
| Maximum                  | 28.580     | 32.20      | 27.60      | 28.20      |
| Mean±SEM                 | 7.910±0.35 | 8.46±0.36  | 7.72±0.35  | 7.97±0.35  |
| p-value                  |            | 0.2816     | 0.7028     | 0.9044     |
| Difference between means |            | -0.55±0.51 | 0.19±0.49  | -0.06±0.49 |
| 95% confidence interval  |            | -1.54-0.45 | -0.78-1.15 | -1.04-0.92 |
| Precision                |            | 1.042      | 0.9529     | 1.312      |

Data are presented as either number or Mean±SEM. The various glucose meter were compared to the WHO recommended manual glucose oxidase method using unpaired t-test. GOD: Glucose oxidase method, SEM: Standard error of the mean

figure, venous blood was used for the reference God and capillary blood was used for the various glucose meters. The bias was however the same when venous blood was used for both the reference method and the Accu-chek (-0.5) (Fig 1b). The 95% limit of agreement was -2.4 to 1.3 (Fig 1b). From this study, whether venous or capillary sample was used for Accu-chek, it was generating results which were much higher than that of the reference method.

When venous blood sample used for the reference God method was compared to the capillary sample used for the Onetouch using Bland-Altman analysis, the bias was -0.1 and the 95% limit of agreement was -2.6 to 2.5 as shown in Figure 2a. The reading from the Onetouch was slightly higher than that of the reference God in agreement with the earlier observation in Table 1. However, when the same venous sample was applied for both the reference method and the ONETOUCH, the bias increased by about 1000% (i.e., -1.0) and the 95% limit of agreement was -2.94 to 0.96 (Fig 2b).

Sensocard gave a bias of 0.2 and 95% limit of agreement of -1.7 to 2.1 (Fig 3a) when its capillary results was compared to the venous reference manual method using Bland-Altman analysis. The SENSOCARD from this study was generating values lower than that generated by the reference manual method. This is also in line with the earlier observation in Table 1. However, when the same venous sample was used for both reference method and the SENSOCARD, the bias increased by -700% and the 95% limit of agreement was -4.3 to 1.4 (Fig 3b). Interestingly, the SENSOCARD gave higher reading when the same venous sample was used.

As shown in Fig 4a, when the results of the venous as well as capillary blood sample from the same 40 subjects were compared for each glucose meter using an unpaired t-test, there was no statistically significant difference for each of the glucose meters. However, when the mean value of the venous blood sample results from each glucose meters was compared to the reference manual God, there was a significant decrease in the

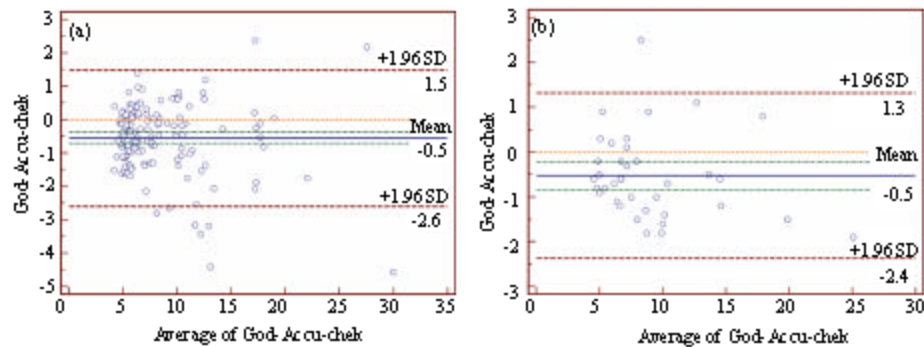


Fig 1: Bland-Altman graphs of difference scores for Accu-chek and the laboratory WHO recommended manual God values (a) in 150 subjects and (b) in 40 subjects

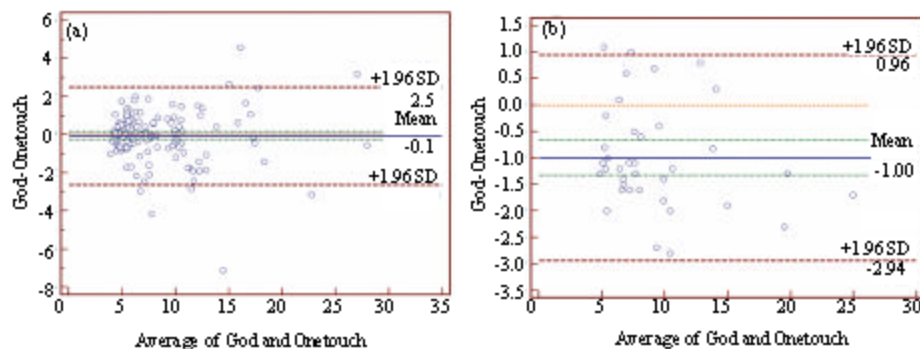


Fig 2: Bland-Altman graphs of difference scores for Onetouch and the laboratory WHO recommended manual God values (a) in 150 subjects and (b) in 40 subjects

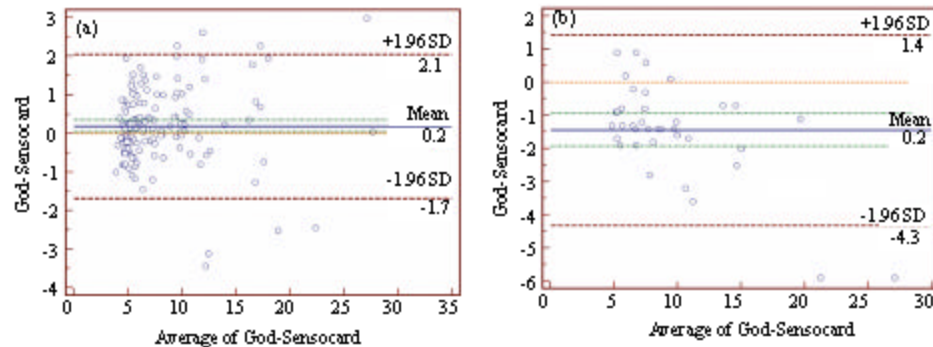


Fig. 3: Bland-Altman graphs of difference scores for Sensocard and the laboratory WHO recommended manual God values (a) in 150 subjects and (b) in 40 subjects

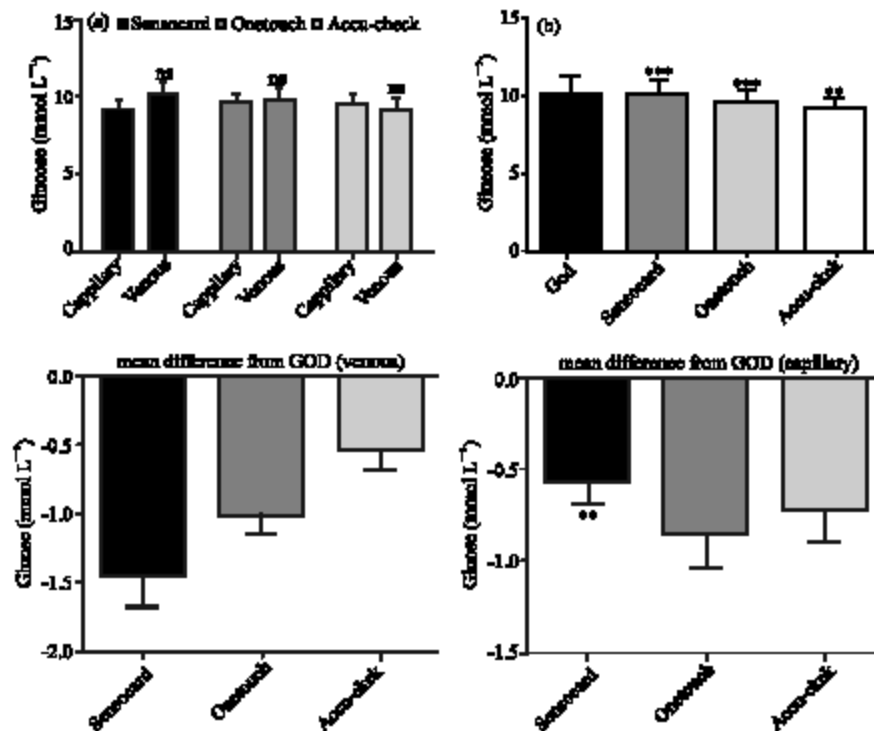


Fig. 4: Mean±SEM of glucose generated by the various glucose meters from different samples. (a) is the value generated when the glucose meters were applied for venous as well as capillary samples from the same 40 subjects (Comparison was done using unpaired t-test). (b) is the value generated when the venous results of the various glucose meter was compared to the reference God using paired t-test. (c) is the mean difference of the venous results from the various glucose meters from that of the reference God. (d) is the mean difference of the capillary results from the various glucose meters from that of the reference God

results generated by the various glucose meters using paired t-test. The p-value was less than 0.0001 for Sensocard and Onetouch; it was less than 0.001 for Accu-check advantage (Fig. 4b). When the mean difference from the reference manual GOD for each glucose meter using venous sample (Fig. 4c) was compared to the mean

difference using capillary blood sample (Fig. 4d), only Sensocard indicated a significant difference from the unpaired t-test ( $p < 0.001$  in Fig. 4d).

As indicated in Table 2, when the glucose results from the 150 subjects were stratified into  $< 3.3$ ,  $3.3-16.67$  and  $> 16.67$  mmol L<sup>-1</sup>, the reading of the Accu-check

Table 2: Distribution of the mean difference of God and glucose meters readings at different cut offs of WHO GOD manual reference method level with 95% confidence interval for mean difference

| Parameters               | Glucose level (mmol L <sup>-1</sup> ) |            |            |
|--------------------------|---------------------------------------|------------|------------|
|                          | <3.3                                  | 3.3-16.67  | >16.67     |
| <b>God</b>               |                                       |            |            |
| Mean±SEM                 | 3.11±0.24                             | 7.08±0.22  | 20.16±1.37 |
| <b>Accu-check</b>        |                                       |            |            |
| Mean±SEM                 | 4.50±0.05                             | 7.64±0.24  | 20.48±1.63 |
| Difference between means | -1.31±0.25                            | -0.55±0.33 | -0.32±2.14 |
| 95% confidence interval  | -2.31-0.22                            | -1.20-0.10 | -4.81-4.18 |
| p-value                  | 0.0348                                | 0.1000     | 0.8842     |
| <b>Sensocard</b>         |                                       |            |            |
| Mean±SEM                 | 3.93±0.10                             | 6.91±0.22  | 19.68±1.38 |
| Difference between means | -0.65±0.26                            | 0.18±0.32  | 0.48±1.95  |
| 95% confidence interval  | -1.47-0.48                            | -0.44-0.80 | -3.61-4.58 |
| p-value                  | 0.1317                                | 0.5737     | 0.8069     |
| <b>Onetouch</b>          |                                       |            |            |
| Mean±SEM                 | 3.81±0.10                             | 7.19±0.24  | 19.44±1.52 |
| Difference between means | -0.65±0.24                            | -0.11±0.33 | 0.72±2.04  |
| 95% confidence interval  | -1.74-0.43                            | -0.76-0.54 | -3.58-5.02 |
| p-value                  | 0.1317                                | 0.7458     | 0.7279     |

Data are presented Mean±SEM. The various glucose meter were compared to the WHO recommended manual glucose oxidase method using unpaired t-test. GOD: Glucose oxidase method, SEM: Standard error of the mean

Advantage gave a significantly ( $p = 0.0348$ ) increased value ( $4.50 \pm 0.05$ ) as compared to that of the reference method ( $3.11 \pm 0.24$ ) at the hypoglycaemic range. That of the Sensocard ( $3.93 \pm 0.10$ ) and Onetouch ( $3.81 \pm 0.10$ ) did not give any significant difference ( $p = 0.1317$  in both instances) as compared to the reference method at the hypoglycaemia range. None of the glucose meters gave glucose values that were significantly different from that of the manual reference method at both the normoglycaemia and hyperglycaemia range (Table 2).

## DISCUSSION

The use of self monitoring blood glucose meters has been recommended to assist patients in achieving glycaemic control (ADA, 2002). Many patients do not use their glucose meter, however, because of the physical and psychological discomfort associated with the traditional finger-stick method (ADA, 2002; Harris *et al.*, 1993). Other body areas used for testing, such as the forearms, thighs, abdomen and calves, are less sensitive than the fingertips (McGarraugh *et al.*, 2001). This study evaluated the accuracy and precision associated with the use of three popular alternative-site blood glucose monitors, Accu-check Advantage, Onetouch Horizon and Sensocard, using forearm venous blood samples and capillary blood samples.

From this study, bias and precision of the glucose meters were minimal across the range of predominantly normal to high glucose values studied ( $3.1$ - $28.6$  mmol L<sup>-1</sup>). Accu-check Advantage and Onetouch Horizon values

differed from the laboratory glucose value by  $1.0$  mmol L<sup>-1</sup> or greater in 1 of 3 patients (29.3 and 30.7%, respectively) for capillary samples and in 1 of 4 (24.7%) for Sensocard. Even though precision was statistically good, this percentage is quite worrying, since there was poor agreement between capillary and venous blood glucose estimation using glucose meters designed for capillary samples (Funk *et al.*, 2001) as confirmed by this study. These findings highlight the need for caution when using glucose meter values to guide insulin dosing with narrowly defined insulin administration protocols regardless of the lack of significant differences between the glucose meter and laboratory reference methods for glucose analysis and the small bias and precision of the glucose meter devices.

Though the discrepancies between various glucose meters and laboratory reference glucose values were not statistically significant from this study, the magnitude of these differences could be considered clinically significant if the glucose values could change treatment decisions in a situation requiring precise glucose measurements. Despite the fact that the bias and precision in this study were minimal and about the same for each glucose meter, they could easily result in erroneous insulin dosages because their difference were as large as  $4.56$ ,  $7.11$  and  $3.43$  mmol L<sup>-1</sup> for Accu-check Advantage, Onetouch Horizon and Sensocard, respectively. Other studies have reported that differences between glucose measurements in blood are not constant but vary according to sample type, analysis and timing of collection (Farrer *et al.*, 1995; Kuwa *et al.*, 2001; Neely *et al.*, 1991).

All the glucose meters in this study demonstrated similar precision, a finding which is consistent with results from previous precision analyses (Thomas *et al.*, 2008; Rivers *et al.*, 2006). The differences in glucose meter readings could be clinically significant at blood glucose values below or at the lower end of the normal glucose range.

The same bias indicated by Accu-check Advantage in both capillary and venous blood samples confirm the manufacturers protocol which states that, glucose measurements can be made using fresh capillary, arterial, or neonatal blood, as well as in heparin (lithium or sodium) or EDTA-anticoagulant venous blood (Accu-check Advantage user manual, 2007). It should be noted that the least glucose value recorded by this study is  $3.1$  mmol L<sup>-1</sup> (Table 1) as such it is not possible to conclude from this study whether it would be accurate beyond this value. The linearity range of Accu-check Advantage as quoted by the manufacturer is  $1.1$ - $33.3$  mmol L<sup>-1</sup>. Accu-check Advantage, however, over estimated both hypoglycaemia and hyperglycaemia in this study.



Since, hypoglycaemia is associated with irreversible brain damage, Accu-chek Advantage could give diabetic patients on therapy a false sense of security even if their glucose level is very low and require some form of intervention which is confirmed statistically. Even though at the high level, its reading is higher than God and the other methods, it is not statistically significant. Since the blood glucose concentration at which significant neurological changes occur is so uncertain (Aynsley-Green, 1991; Suh *et al.*, 2007), it would be prudent to either avoid the use of glucose meters altogether for infants at risk of hypoglycaemia or to treat estimations so obtained with real suspicion unless confirmed by laboratory estimations.

The observed 1000 and 700% increase in bias for Onetouch Horizon and Sensocard, respectively when testing with capillary and venous blood was compared is also in agreement with the manufacturers protocol which emphasizes the use of only fresh capillary whole blood and not serum nor plasma nor venous blood (Onetouch Horizon user manual, 2004; Sensocard user manual, 2008). Because the minimum glucose reading from this study was above  $1.1 \text{ mmol L}^{-1}$  (Onetouch Horizon user manual, 2004; Sensocard user manual, 2008) it can not be inferred whether these meters can accurately estimate a low reading of  $1.1 \text{ mmol L}^{-1}$ . Precision for Sensocard in this study was approximately 1.0% (Table 2) which is good since the manufacturer states 3.42% in its user manual. These significant increases in bias when venous samples was applied to Onetouch and Sensocard over the capillary sample is in agreement with the reports of other investigators who found significant differences between fingertip and alternative-site measurements (Ellison *et al.*, 2002; Jungheim and Koschinsky, 2002). Alternative-site testing, while appropriate during steady-state blood glucose concentrations (e.g., fasting and preprandial), may significantly lag behind blood glucose values obtained from finger-stick testing during times of rapid blood glucose change (e.g., postprandial and post-insulin administration) (Ellison *et al.*, 2002; Jungheim and Koschinsky, 2002; Lucidarme *et al.*, 2005).

It has also been stated by the Clinical and Laboratory Standards Institute (2002) that glucose concentrations may differ among different specimen types collected at the same time from the same individual. For example, capillary glucose concentrations may be up to  $20\text{-}30 \text{ mg dL}^{-1}$  ( $1.1\text{-}1.7 \text{ mmol L}^{-1}$ ) higher than venous concentrations in an individual who has recently ingested food and/or liquids/beverages/drinks.

Two readings out of the 40 subjects gave a high reading which exceeded the highest value which could be estimated by the glucose meters which is  $33.3 \text{ mmol L}^{-1}$  (Accu-chek user's manual 2007, Onetouch Horizon users

manual 2004 and SENSOCARD user's manual 2008). This affirms the fact that glucose meters have limitations in estimating extremely low and high glucose values, hence the conventional laboratory manual glucose oxidase method cannot be ruled out completely no matter the turn about time and cost considering other factors.

## CONCLUSION

All blood glucose meters used in this study demonstrated similar precision. However, the Accu-chek Advantage has the tendency to overestimate hypoglycaemic levels of blood glucose. The Accu-chek Advantage is capable of estimating both capillary and venous blood glucose to the same level of accuracy. Onetouch Horizon and Sensocard are however incapable of efficiently determining venous blood glucose and should not be utilised in clinical settings for venous blood glucose estimation.

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