ORIGINAL ARTICLE

Glucose measurement: Comparison of venous and capillary glucose measurements in type II diabetes mellitus.

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ABSTRACT… Objective: To determine the comparison between the capillary glucose and venous plasma glucose in type II diabetic patients. **Study Design:** Cross Sectional Observational study. **Setting:** Al–Tibri Medical College and Hospital Karachi. **Period:** 1st January 2020 to 30th April 2020. **Material & Methods:** A total of 86 diabetic patients from the out-patient department with non-probability consecutive sampling were selected. Subjects were diagnosed cases of type II diabetes based on the screening recommendation by the American Diabetes Association between 35-75 years of age of either gender included in this study. Patients with type I diabetes, pregnant females and hematocrit of more than 55% or less than 35%, and patients taking medications like Acetaminophen, and Ascorbic acid were excluded from the study. Each participant was measured for the capillary blood glucose levels by using Accu Chek, Easy max and On-call EZII, using strips by Glucose Oxidase Method. A venous sample was collected within 5 minutes of finger-prick test in a sodium fluoride tube. A Statistical Package for Social Sciences version 22 was used for data analysis. **Results:** Out of 86 patients in the study, 48(55.8%) were females and 38((44.2%) were males with a mean age of 47.16±9.916. The mean blood sugars by venous plasma glucose were 249.58±110.75 mg/dl, by Accu Chek 250.47±117.071 mg/dl, by EasyMax 259.26±119.751 mg/dl, and by On-call EZII 249.33±124.380 mg/dl which shows statistically significant correlation with a p value of <0.001. The glucometers accuracy was determined by using Error grid analysis showed a strong positive correlation between the Accu Chek R^2= 0.917, EasyMax R^2= 0.917, and Oncall glucometers R^2= 0.868 with venous plasma glucose with a statistically significant (p <0.001). **Conclusion:** This study shows a strong positive correlation between capillary and venous glucose measurements.

Key words: American Diabetes Association, Capillary Blood Glucose, Glucometers, International Standardization Organization, Type II Diabetes, Venous Plasma Glucose.

INTRODUCTION

Diabetes Mellitus is one of the non-communicable diseases whose prevalence is rising globally. In Pakistan, the prevalence of Type II diabetes is 7.6%-11%, and an estimated increase of 15% is predictable in 2030, which will rank Pakistan 7th in World Health Organization (WHO) prevalence list.[1,2] Diabetes mellitus is a significant general medical condition, and its complications can be deferred by self monitoring of blood glucose (SMBG). The American Diabetes Association (ADA) has recommended the SMBG as the key component of diabetes management.[3] SMBG is usually suggested for type I diabetes. It is also recommended that fasting and postprandial blood glucose levels should also be monitored with type 2 diabetes.[4,5]

SMBG is valuable, nevertheless, when the glucose information is gathered in an organized way, interpreted precisely, furthermore, used to make proper helpful actions for management. The International Diabetes Federation (IDF) suggests that initially, periodically, and over short periods, SMBG be performed to get glucose profiles that are illustrative of everyday glucose drive.[6] Capillary blood glucose testing is ecnomical, less invasive to obtain, and an easier method as an alternative to venous plasma samples.[7] Glucometers are easily availabale in the market in different brands, and shockingly notwithstanding the expanding utilization of these gadgets, setting the norm for

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their right use has been questionable.[8] There is a noteworthy variation among glucometers devices, despite the advances in technology, which has entailed the accuracy of performance guidelines by organizations such as the International Standardization Organization (ISO) and American Diabetes Association (ADA). The ISO recommend accuracy criteria for values <100 mg/dl to ±10 mg/dl and for values >100mg/dl to ±20%, while ADA endorsed ±5% variation for all values.[9,10]

Multiple studies were conducted to evaluate the efficacy of glucometers in contrast with a standard laboratory method. However, in Pakistan, we found only one study concerning the precision of glucometers in association with laboratory methods in outpatient settings.[3] The rationale of the current study was to analyze the capillary blood glucose measurements acquired by three commonly used glucose meters and to decide the precision of those estimations comparative with serum blood glucose values in our setup.

MATERIAL & METHODS

This cross-sectional observational study was accompanied at Outpatient Department of Medicine in Al–Tibri Medical College and Hospital Karachi from 1st January 2020 to 30th April 2020. Non-probability sampling technique was used for the selection of the participants. The Institutional Review Board approval (ATMC/IREC/2017/00014) was attained earlier to the initiation of the study. A total of 86 diabetic patients from outpatient settings were selected. Subjects of diagnosed cases of type II diabetes based on the screening recommendation by the ADA, between 35-75 years of age of either gender were included in this study. Patients with type I diabetes, pregnant females and hematocrit of more than 55% or less than 35%, patients taking medications with Acetaminophen, and Ascorbic acid were excluded from the study. After taking written consent from the subjects, data were collected on a proforma especially designed for this study, which included age, gender, duration of diabetes, and details of oral hypoglycemic agents (OHA) and /or use of insulin recorded at the baseline.

Capillary blood samples from the finger and consecutive drops of blood were applied to each meter, using a single finger prick site and venous blood samples from a right antecubital vein taken simultaneously at the time of visit to OPD. The capillary blood glucose levels were measured with On-Call EZII, Accu Chek, and Easy max using strips by the Glucose Oxidase Method. A venous sample was collected within 5 minutes of the finger-prick test in a sodium fluoride tube. The laboratory measured the plasma glucose on the MICROLAB 300 using the Glucose Oxidase method within ± one and half hours of sample collection. Three hospital-based glucometers, On-Call EZII, Accu Chek, and Easy max were compared with the laboratory readings and entered in proforma.

Data entry and analysis were performed with a statistical package for social sciences (SPSS) version 22. Descriptive analyses were measured as mean values. Clarke error grid analysis and Bland and Altman graph were analyzed to find agreement between venous plasma glucose and capillary blood glucose of three glucose meters.[11,12] The R^2 value was used to assess the correlation between three glucose meters and $P < 0.05$ was considered statistically significant.

RESULTS

A total of 86 adults participated in the study. Out of 86, 48(55.8%) were females, and 38((44.2%) were males with a mean age of 47.16±9.916. Duration of diabetes of less than 5 years was present in 46(53.5%) while more than 5 years present in 40(46.5%), as shown in Table-I. The study subjects showed mean blood sugars by VPG was 249.58±110.75, by Accu Chek was 250.47±117.071, by Easy max 259.26±119.751, by On-call EZII 249.33±124.380 with p-value significant of <0.001 as shown in Table-II.

The glucometers accuracy was determined by Error grid analysis [Figure-1] and Bland Altman scatter plots [Figure-2]. The R^2-value shows a strong positive correlation between the Accu Chek R^2= 0.917, Easy max R^2= 0.917, and On-call EZII glucometers R^2= 0.868 with venous plasma glucose with a p-value significant of <0.001 as shown in Figure-1.

|	Minimum RBS (mg/dl)	Maximum RBS (mg/dl)	RBS Mean±SD (mg/dl)	P-Value
VPG	75	580	249.58±110.75	<0.001
Accu Chek	80	573	250.47±117.07	<0.001
Easy max	82	601	259.26±119.75	<0.001
On-Call EZII	57	574	249.33±124.38	<0.001

Table-I. Comparison of demographic and clinical characteristics of diabetics in outpatient department (N=86)

Variables		Number of Patients (n=86)
Gender	Male Female	38(44.2%) 48(55.8%)
Diabetes duration	<5 years >5 years	46(53.5%) 40(46.5%)
Use of Hypoglycemic agents	Only OHA Only Insulin Insulin and OHA	64 (74.41%) 10(11.62%) 12(13.95%)

Table-II. Mean RBS of venous plasma glucose and different glucometers (N=86)

$Y = 1.012x - 2.147$
$R^2 = 0.917$
$P < 0.001$

(a)


$Y = 1.046x - 11.852$
$R^2 = 0.868$
$P < 0.001$
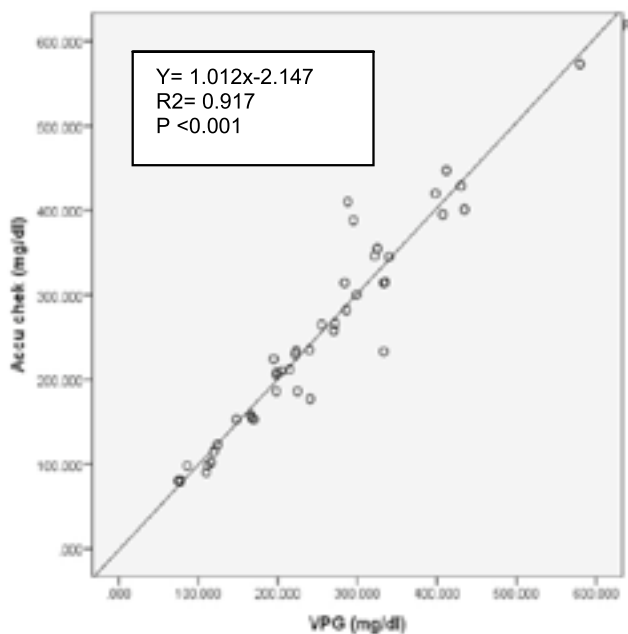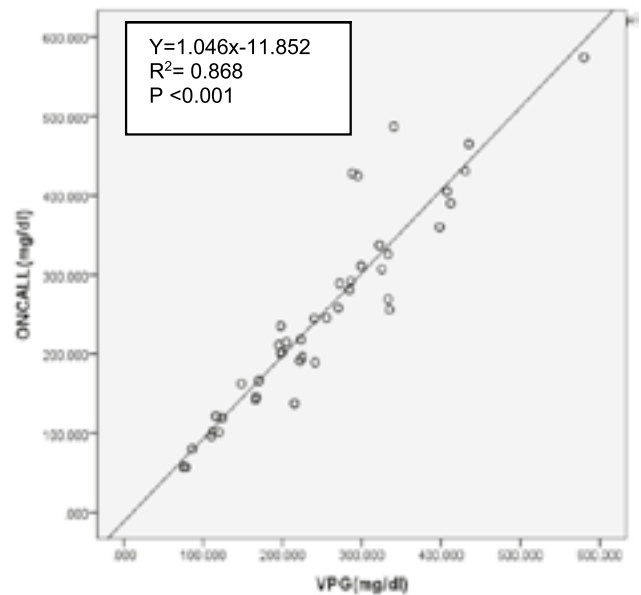
(b)

The degree to which the glucometers strayed from the reference technique is addressed in the Bland Altman scatter graph. We examined our results utilizing standards of ISO and found that it was meeting those standards, and a large portion of the values was falling inside the acceptable boundary as represented in Figure-2.

Acceptable boundary: 62 (72.1%) Acceptable boundary: 52 (60.5%) Acceptable boundary: 54 (62.8%)
Undesirable boundary: 24 (27.9%) Undesirable boundary: 34 (39.5%) Undesirable boundary: 32(37.2%)

Figure-2. Scatter plot of Accu Chek, Easy max and On-Call EZII glucometers with venous plasma glucose levels (n=86)
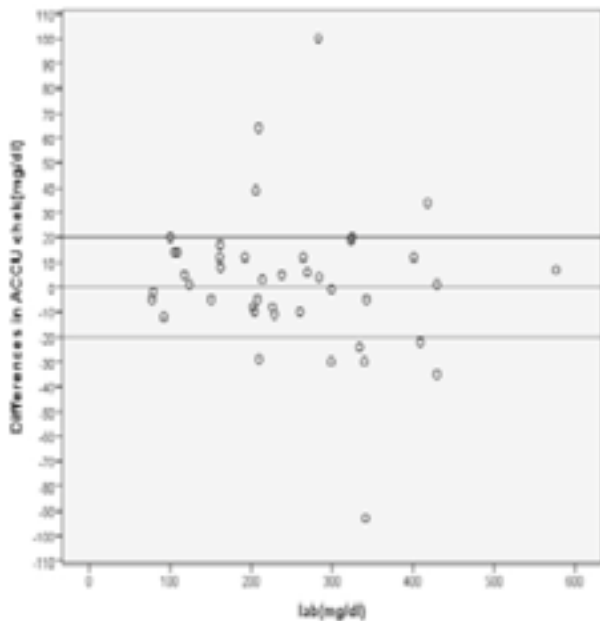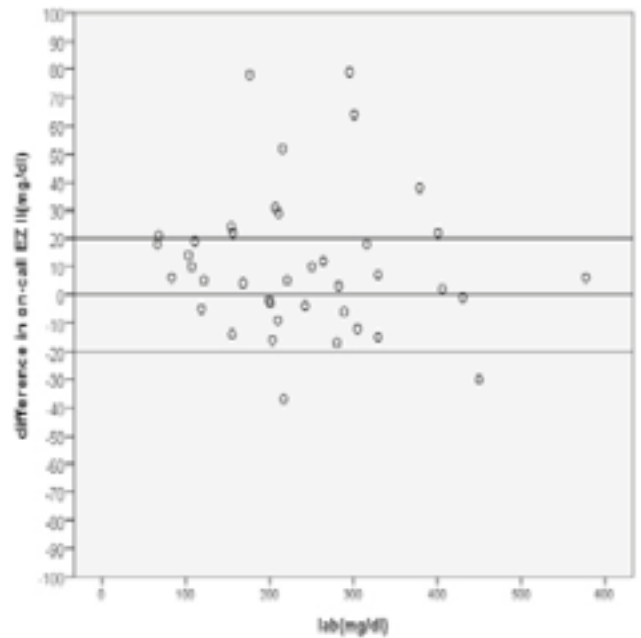
Y=1.042x-0.751
R2= 0.928
P <0.001
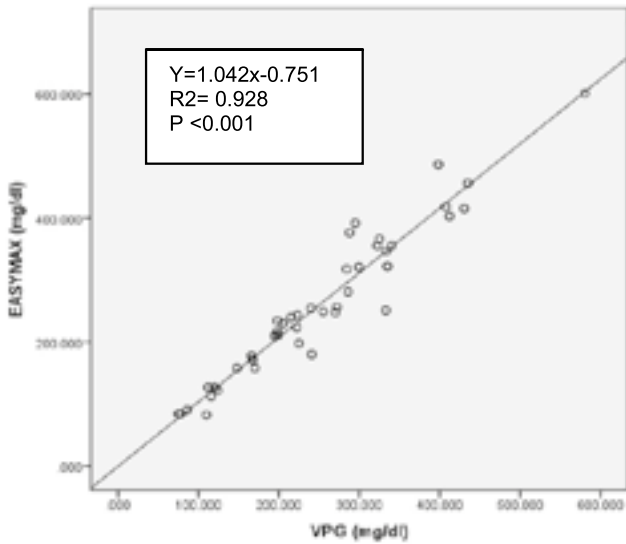
(c)

Figure-1. Correlation coefficients of Accu Chek, Easy max and On- Call EZII glucometers with venous plasma glucose levels
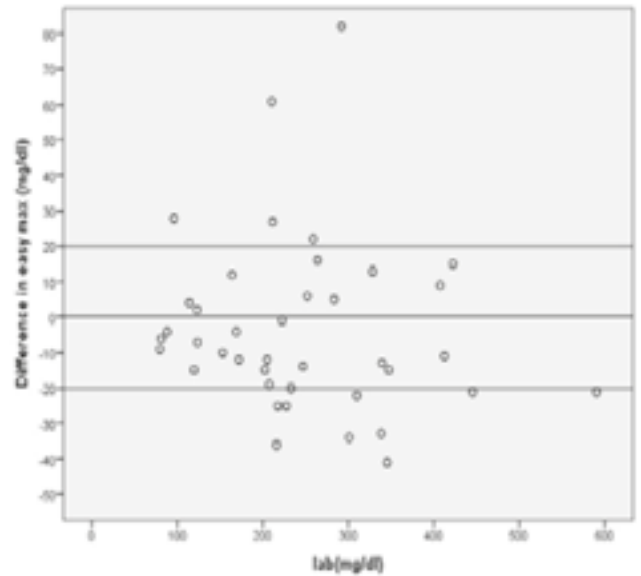
(b)

(a)

(c)

DISCUSSION

On regular basis, the monitoring of blood glucose is exceptionally helpful in preventing hypoglycemia and adjusting the treatment of patients. For diabetes care and management, the SMBG using reagent permeated is a modest and fundamental constituent.[13] Precise assurance of blood glucose is significant for monitoring in both inpatients and outpatients settings as erroneous values can consequence in clinical misinterpretation with severe outcomes. Such errors can bring about flawed decisions in regards to glucose meter precision when samples from these sources are utilized to assess execution.[14,15]

The mean ± SEM of the venous blood glucose estimated by the standard strategy and blood glucose estimated by glucometers were

statistically significant with a p-value of <0.001. This study was in agreement with Mitra et al. (p<0.05).[16] This finding was in contrast to Bhurayanontachai, with a p-value of 0.1. This variation in values is probably caused by the disease severity of patients admitted to Medical ICU (MICU).

The study findings in our study showed that that the blood glucose levels were ranging from euglycemia to hyperglycemia, and only one case reported hypoglycemia while in the previous study, euglycemia was reported in the majority of participants so the hypoglycemia and hyperglycemia correlation with capillary and venous blood glucose was missed in the MICU patients.[17]

The present study is consistent with prior findings of the arterial glucometer showed a sturdy agreement with the venous blood glucose, as determined by Bland-Altman analysis, which gave a significant correlation.[16,18] These findings can be altered by certain factors like technique, technical staff, and hematocrit status.

The international recommendations set by the ISO for technical accuracy were met accurately all of the three glucometers consistently in this study.[19] This study collaborated with Mitra S study[16] while was a disparity of 35% among capillary and venous blood glucose levels in a study conducted in Taiwan by Yang et al.[20] The reason for disparity might be due to differences in sample size, demographics, time and technique of the sampling.

The meticulousness and correctness of glucometers have enhanced over time. Anyway, there are still worries concerning glucometers standardization. It is realistic to achieve the comparison between the glucometers and venous glucose through ISO criteria, as, among the various guidelines, it seemed to be more practical as compared to the ADA.[21]

Limitations of this study include firstly, small sample size and single-centered-based study hence results could not be applied generalized.

Secondly, glucose samplings were collected once for each participant so it's likely that an error at the machine level could occur in some samples and may alter the results.

CONCLUSION
This study shows a strong positive correlation between capillary and venous glucose measurements. Undoubtedly, the use of blood glucose monitoring in clinical settings and ambulatory care has improved over the years and is likely to decrease the worse outcomes of the patients.
**Copyright© 17 Feb, 2022.**

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AUTHORSHIP AND CONTRIBUTION DECLARATION

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2	Shamaila Tasleem	Literature review, Manuscript writing, Data collection.	
3	Abdul Rabb Bhutto	Manuscript writing, Interpretation of data, Proof reading.	
4	Muneer Sadiq	Literature review, Data collection.	