

ORIGINAL ARTICLE

Medicine Science Med Science 2018;7(1):218-21

Verification studies in glucometers: Should we use capillary blood or venous blood for comparison?**Canan Topcuoglu¹, Fatma Meric Yilmaz², Oguzhan Kaya¹, Bagdagul Cakir¹**¹Ankara Numune Training and Research Hospital, Clinical Biochemistry Laboratory, Ankara, Turkey²Yildirim Beyazit University Medical Faculty Biochemistry Department, Ankara, Turkey

Received 27 September 2017; Accepted 21 November 2017

Available online 20.12.2017 with doi: 10.5455/medscience.2017.06.8696

Abstract

Glucometers are widely used in the diagnosis of blood glucose levels in patients with diabetes mellitus. EN ISO 15197 suggests that glucometer comparison studies should have 100 capillary blood samples be worked on at least twice. In this study, we planned on comparing the glucose results measured in a routine biochemistry analyzer from two different glucometers, capillary and venous blood samples, and aimed to discuss the effects of blood taking systems on the glucometer validation studies. Capillary and venous blood samples were taken from 101 individuals and their glucose concentrations measured simultaneously using two different glucometers (Accu-chek and GlucoMax). Capillary and venous blood samples were centrifuged after clotting and analyzed in the Roche P modular system. In the fasting condition, the equations for regression analysis that were found $y=0,873x+24,32$ ($r=0,857$) in between Accu-chek and venous blood glucose, $y=0,9x+16,15$ ($r=0,920$) in between Accu-chek and capillary blood glucose, $y=0,811x+20,94$ ($r=0,776$) in between GlucoMax and venous blood glucose, and $y=0,851x+12,28$ ($r=0,863$) in between GlucoMax and capillary blood glucose. In the postprandial state, the equations were $y=0,713x+48,46$ ($r=0,258$) in between Accu-chek and venous blood glucose, $y=0,981x+11,77$ ($r=0,718$) in between Accu-chek and capillary blood glucose, $y=0,706x+39,12$ ($r=0,453$) in between GlucoMax and venous blood glucose, and $y=0,790+22,35$ ($r=0,787$) in between GlucoMax and capillary blood glucose. In the fasting and postprandial state, the capillary glucose levels showed better correlation with glucometer measurements than venous blood glucose levels. In glucometer verification studies, capillary blood obtained with capillary blood sampling systems and used instead of venous blood should be the preferred sample.

Keywords: Capillary blood, venous blood, glucometer**Introduction**

In our current day, Diabetes Mellitus (DM) and its complications take its place as one of the primary causes of death. American Diabetes Association recommends the use of glucometers in order to reduce the complications related to poor glycemic control in DM patients [1]. The main advantages of glucometers are their practical use, showing results in a very short time and small amount of samples being sufficient for analysis [2]. However, it is important to compare the results of the glucometer with the results from the central laboratory. There have been many studies which compare the glucose results from the glucometer with the glucose results from the central laboratory and venous blood samples were used in most of these studies [3-7]. EN ISO 15197 suggests that the studies of glucometer verification should be conducted with at least 100 capillary blood samples [8]. In addition, for glucose measurement in routine biochemical analysis devices serum or plasma is used mostly and capillary blood is not used.

It can be difficult to draw venous blood from children, elderly and dehydrated patients. Moreover, stasis and hemolysis that occur after applying tourniquet for a long time affect the results of the analysis. In order to use on these patients, tubes that are 500-600 μ L and that assist to draw capillary blood samples have been developed.

In this study, we aimed to compare two different glucometer glucose results with the venous and capillary blood glucose results measured in routine biochemical analyzers and to discuss the effect of the sample that is used in glucometer comparison studies.

Material and Methods

The study was conducted in Ankara Numune Training and Research Hospital, Biochemistry Clinic. Approval of ethics committee was obtained from Ankara Numune Training and Research Hospital. Capillary blood and venous blood samples were collected from 101 volunteer subjects; their glucose concentrations were measured simultaneously with two different glucometers. Accu-check Active (Roche Diagnostics, Germany) and GlucoMax TD-4227 (TaiDoc Technology Corporation, Taiwan) glucometers were used for measuring glucose from the fingertip. Venous

*Corresponding Author: Canan Topcuoglu, Ankara Numune Training and Research Hospital, Clinical Biochemistry Laboratory, Ankara, Turkey

E-mail: drcanantopcuoglu@gmail.com

samples were drawn to serum separator tubes, and the capillary blood samples were drawn to capillary tubes (BD Microtainer gel tube, BD Diagnostics, USA) by the dipsticks from the fingertip. After the coagulation was complete, capillary and venous blood samples were centrifuged for 10 minutes in 1300 g and their glucose levels were measured in the Hitachi P Modular Systems (Roche Diagnostic Germany) biochemical analyzer that was in our laboratory. For both devices, the imprecision study was performed with two levels of quality control solution.

Statistical analysis

Correlation analyses were carried out using Microsoft Office Excel 2007. For Bias%; (Glucometer glucose – Laboratory glucose) / Laboratory glucose*100 formula was used.

Results

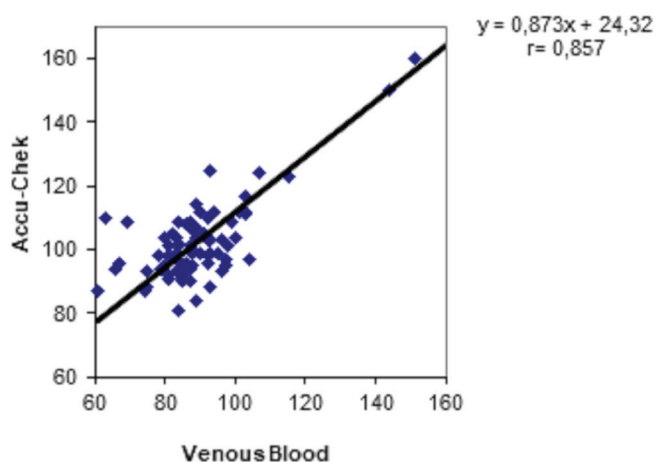
Of 101 samples taken from volunteer subjects, 81 were taken in fasting state, and 20 were taken in postprandial state.

In the study of imprecisions that was conducted with two levels of quality control samples, for CV%; with Accu-chek Active 60.3 mg/dL and for 168.05 mg/dL concentration; 3.44%, 2.36%, respectively, and with GlucoMax TD-4227 82.45 mg/dL and for 214.42 mg/dL concentration 6.51%, 3.44% have been found respectively.

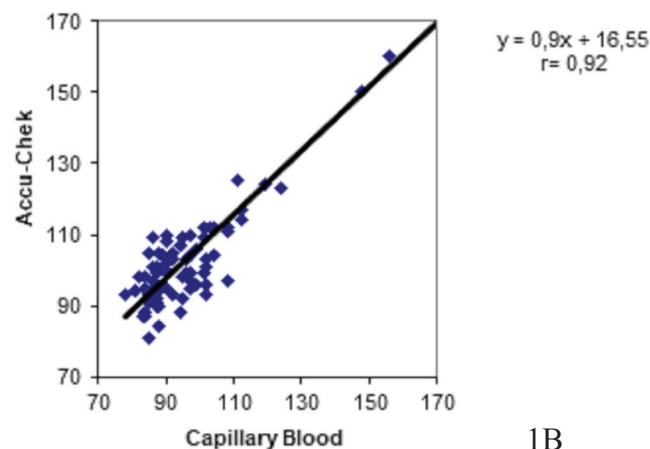
The bias% values of Accu-chek Active and GlucoMax TD-4227 glucose results of fasting and postprandial state according to capillary and venous blood glucose results are shown in Table 1.

Table 1. Bias % of Accu-chek and GlucoMax glucometers compared to venous and capillary blood samples in fasting and postprandial state

	Fasting state		Postprandial state	
	Venous blood	Capillary blood	Venous blood	Capillary blood
Accu-chek	+13.98	+6.99	+19.82	+7.63
GlucoMax	+4.11	-2.26	+9.81	-1.36



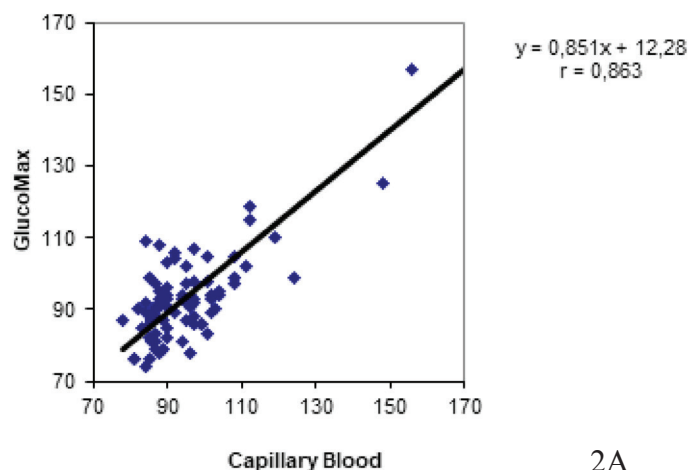
1A



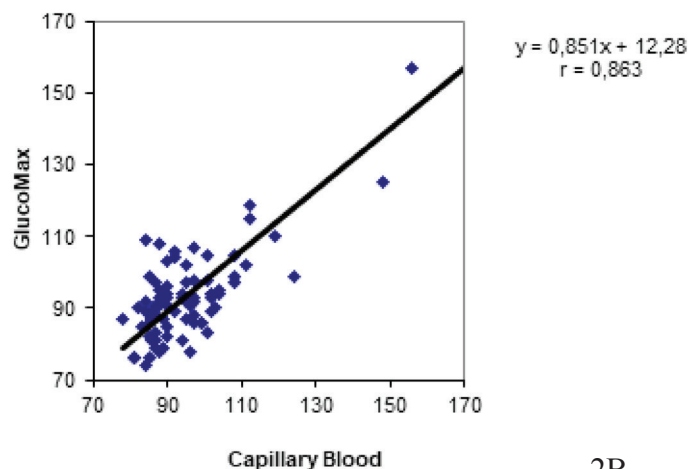
1B

Figure 1. Regression chart for Accu-Chek in the fasting state, A; Accu-chek with venous blood, B; Accu-chek with capillary blood

In regression analysis in fasting state, $y=0,873x + 24,32$ ($r=0,857$) equation between Accu-chek Active glucose and venous blood glucose, $y=0,9x + 16,15$ ($r=0,920$) equation with capillary blood glucose (Figure 1) and $y=0,811x + 2094$ ($r=0,776$) equation between GlucoMax TD-4227 glucose and venous blood glucose, $y=0,851x + 12,28$ ($r=0,863$) equation with capillary blood glucose (Figure 2) were found.

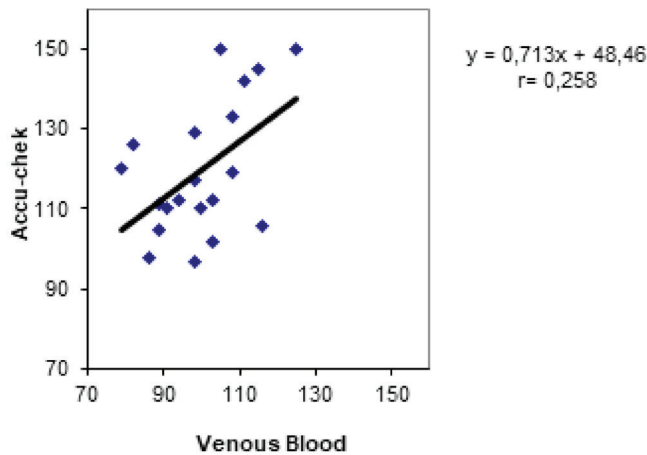


2A

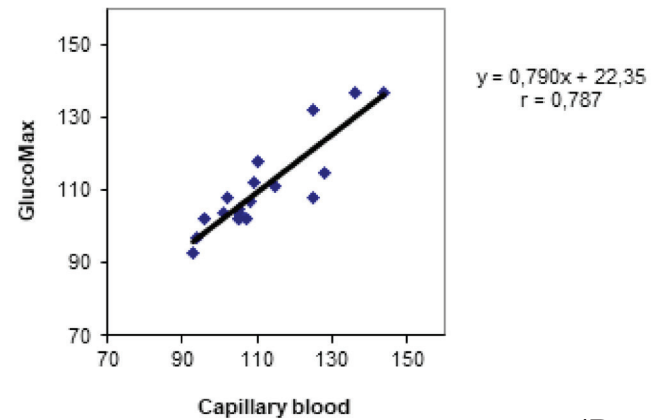


2B

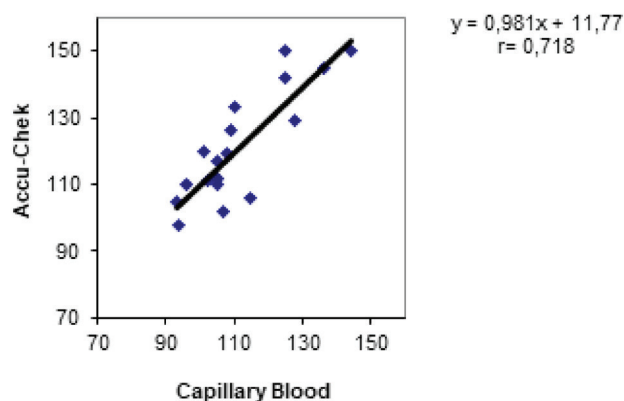
Figure 2. Regression chart for GlucoMax in the fasting state, A; GlucoMax with venous blood, B; GlucoMax with capillary blood



3A



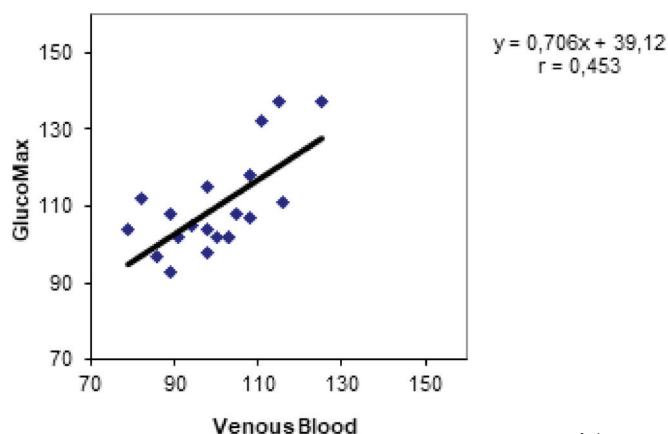
4B



3B

Figure 3. Regression chart for Accu-Chek in the postprandial state, A; Accu-chek with venous blood, B; Accu-chek with capillary blood

With regression analysis in postprandial state, $y=0,713x + 48,46$ ($r=0,258$) equation between Accu-chek Active glucose and venous blood glucose, $y=0,981x + 11,77$ ($r=0,718$) equation with capillary blood glucose (Figure 3), $y=0,706x + 39,12$ ($r=0,453$) equation between GlucoMax TD-4227 glucose and venous blood glucose, and $y=0,790 + 22,35$ ($r=0,787$) equation between capillary blood glucose (Figure 4) were obtained.



4A

Figure 4. Regression chart for GlucoMax in the postprandial state, A; GlucoMax with venous blood, B; GlucoMax with capillary blood

Glucometers are used commonly in both hospitalized and outpatients of DM for the follow-up of glycemic control. It has been shown that 40% of type 1 DM patients, 26% of type 2 DM patients use glucometers at least once a day [6]. For the reliability of the results from glucometers, it is important to compare the results with central laboratory results. In our study, we compared two different glucometer results with central laboratory results using both capillary and venous blood samples. We found that both results of glucometer were more compatible with capillary blood results rather than venous blood results. Similarly, we found that both results of glucometer had lower bias % with capillary blood results compared to venous blood results.

GlucoMax had lower bias compared to Accu-chek Active in both fasting and postprandial states. Bias% of Accu-chek Active for venous blood sample; was +13.98, bias% for capillary blood sample; was +6.99. Bias % values we found for Accu-chek were higher than the study in which Accu-chek Comfort was compared to reference method YSI 2300. In this study, it has been reported that the bias % value in 144mg/dL glucose concentration was -5.1% [2].

In our study, it was seen that the results of Accu-chek Active was better correlated in capillary blood results when compared with venous blood (in fasting state $r=0.920$, $r=0.857$, in post-prandial state $r=0.718$, $r=0.258$ respectively) in both fasting and postprandial states. Similarly, GlucoMax TD-4227 glucose results in both fasting and postprandial states were more compatible with capillary blood results than venous blood results (in fasting state $r=0.863$, $r=0.776$, in postprandial state $r=0.787$, $r=0.453$). In postprandial state, while the correlation between venous blood glucose results of Accu-chek Active and GlucoMax TD-4227 decreased significantly compared to the fasting state, the correlation of capillary blood glucose between the results of Accu-chek Active and GlucoMax was better compared to venous blood. Different results have been found in similar studies conducted earlier. While Funk DI, et. al. found a weak correlation between the capillary and venous blood glucose levels in fasting state [9], it has been found that there was a good correlation between venous and capillary blood samples in bedside glucometers in the emergency services in another study [10].

While the glucose results of Accu-chek Active was higher in both

venous blood and capillary blood results, the glucose results of GlucoMax was higher when compared to venous blood, and lower when compared to capillary blood. It has been shown that the glucose results of Accu-Chek Go are higher than Roche Modular System glucose results and Accu-chek Comfort Curve glucose results are higher than central laboratory venous blood glucose results [6,11]. In another study, glucose results of glucometer were found to be higher than arterial, capillary, and venous blood glucose results [12].

In a study conducted on healthy individuals with 75 gr glucose tolerance test, while venous and capillary blood glucose results in the 0. minute were similar, after glucose uptake, they found that the capillary blood glucose was significantly higher than venous blood glucose. They have emphasized that the glucose consumption rate in the tissues may result from the difference between capillary and venous blood [13]. In our study, it was observed that both glucometer results were higher in postprandial state compared to fasting state in terms of both venous and capillary blood.

Conclusion

The glucose results of GlucoMax and Accu-chek Active in fasting and postprandial states have been found more compatible compared to capillary blood results and venous blood results.

Limitations

The low number of samples taken from the postprandial state was the limitation of our study.

Declaration of Conflicting Interests

The authors declare that they have no conflict of interest.

Financial Disclosure

No financial support was received.

References

1. Looie RF, Tang Z, Sutton DV, Lee JH, Kost GJ. Point-of-care testing effects of critical variables, influence of reference instruments, modular glucose meter design. *Arch Pathol Lab Med.* 2000;124(2):257-66
2. Khan AI, Vasquez Y, Gray J, Wians FH Jr, Kroll MH. The variability of results between point-of-care testing glucose meters and the central laboratory analyzer. *Arch Pathol Lab Med.* 2006;130(10):1527-32.
3. Marley JV, Davis S, Coleman, Hayhow BD, Brennan G, Mein JK, Nelson C, Atkinson D, Maguire GP. Point-of-care testing of capillary glucose in the exclusion and diagnosis of diabetes in remote Australia. *Med J Aust.* 2007;186(10):500-3.
4. Püntmann I, Wosniok W, Haeckel R. Comparison of several point-of-care testing (POCT) glucometers with an established laboratory procedure for the diagnosis of type 2 diabetes using the discordance rate. A new statistical approach. *Clin Chem Lab Med.* 2003;41(6):809-20.
5. Robinson CS, Sharp P. Tighter accuracy standards within point-of-care blood glucose monitoring: how six commonly used systems compare. *Journal of Diabetes Science and Technology.* 2012;6(3):547-54.
6. Hawkins RC. Evaluation of Roche Accu-Chek go and Medisense Optium blood glucose meters. *Clin Chim Acta.* 2005;353(1-2):127-31.
7. Mraovic B, Schwenk ES, Ebstein RH. Intraoperative accuracy of a point-of-care glucose meter compared with simultaneous central laboratory measurements. *J Diabetes Sci Technol.* 2012;6(3):541-6.
8. International Organization for Standardization. In vitro diagnostic test systems-requirement for blood glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197:2003.
9. Funk DI, Chan L, Lutz N, Verdile VP. Comparison of capillary and venous glucose measurements in healthy volunteer. *Prehosp Emerg Care.* 2001;5(3):275-7
10. Boyd R, Leigh B, Stuart P. Capillary versus venous bedside blood glucose estimations. *Emerg Me J.* 2005;22(3):177-9.
11. Critchell CD, Savarese V, Callahan A, Aboud C, Jabbour S, Marik P. Accuracy of bedside capillary blood glucose measurements in critically ill patients. *Intensive Care Med.* 2007;33(12):2079-84.
12. Petersen JR, Graves DF, Tacker DH, Okorodudu AO, Mohammad AA, Cardenas VJ Jr. Comparison of POCT and central laboratory blood glucose results using arterial, capillary, and venous samples from MICU patients on a tight glycemic protocol. *Clin Chim Acta.* 2008;396(1-2):10-13.
13. Kuwa K, Nakayama T, Hoshino T, Tominaga M. Relationships of glucose concentrations in capillary whole blood, venous whole blood and venous plasma. *Clin Chim Acta.* 2001;307(1-2):187-92.