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Comparison of patient-side capillary glucose measurements with autoanalyzer results

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ABSTRACT

Rapid diagnosis and treatment are essential issues for emergency department (ED) physicians. A glucometer is a biochemical measurement tool used for the rapid diagnosis and the detection of complications that can be lethal for patients with diabetes and differential diagnosis in the ED. Patients who were admitted to our ED between August 2014 and August 2015, had their finger-prick glucose values measured with a glucometer and their blood glucose levels checked simultaneously with an autoanalyzer in our biochemistry laboratory were enrolled in our study. In our study, the correlation coefficients for the capillary blood glucometer glucose versus the laboratory autoanalyzer blood glucose was found to be 0.9654 (95 % confidence interval (CI)). According to Bland-Altman analysis, glucose values were mostly within conformity limits. According to Error Grid analysis, 92.2 % of the participants were in the A zone, 6.7 % were in the B zone 0.97 % were in the D zone. Perhaps another important point is that a new biochemical autoanalyzer, that can yield values very similar to reference values within a short period and allows rapid decision making at the clinical level, needs to be developed.

1. Introduction

Rapid diagnosis and treatment are essential issues for emergency department (ED) physicians. A glucometer is a biochemical measurement tool used for the rapid diagnosis and the detection of complications that can be lethal for patients with diabetes and differential diagnosis in the ED. Doctors use these results as the basis for patients who require a quick response according to their glucose values; after that, these results are compared with those of the routine autoanalyzer, and then the treatment is re-evaluated. It takes much time to re-evaluate the treatment according to the results of the autoanalyzer. Therefore, conformance of the values measured with glucometers to the values considered, as the reference is required regarding the accuracy of the decision for clinical treatment. The 2013 version of ISO 15197 specifies that a bias of 15% might be present in 95% of measurements that are higher and lower than 100 mg/dl compared with reference measurements (ISO 15197, 2013). In addition, according to the American Diabetes Association criteria, bedside glucose results should not show a deviation of more than 5% compared with the reference autoanalyzer results (ADA, 1996). Therefore, bedside glucose measurements must be compared with the results of the autoanalyzer that are considered reference values.

According to the glucometer evaluation criteria of the Clinical and Laboratory Standards Institute, POCT 12-A3 January 2013, 95% of results should be within the ±12 mg/dl range at <100 mg/dl glucose concentrations and within the range of ±12.5% at >100 mg/dl glucose concentration. The number of results deviating more than 15 mg/dl from a glucose value <75 mg/dl and the number of samples deviating more than 20% at glucose concentrations >75 mg/dl should not be more than 2% of all results (Krouwer, 2013).

This study aimed to investigate the comparison of bedside capillary glucose measurements with autoanalyzer results and the accuracy of clinical acceptability.

2. Materials and methods

Our study is a retrospective cross-sectional study. Our hospital is a district government hospital that provides care to approximately 130.000 patients in the ED per year. Patients who were admitted to our ED between August 2014 and August 2015, had their finger-prick glucose values measured with a glucometer and their blood glucose levels checked simultaneously with an autoanalyzer in our biochemistry laboratory were enrolled in our study. In our study, 232 patient files were scanned. Patients with high blood glucose values too high to be measured with an autoanalyzer, glucometer and patients whom we could not obtain blood glucose values with an autoanalyzer were excluded. Data for our study were obtained from the hospital automation system. Blood glucose values and demographic information of patients and their diabetes diagnoses were recorded in our study form. A 'GlucoLeader® Yasee Diabetic Blood Glucose Meter-GLM76' was used in our ED for the measurement of blood capillary glucose levels and an Erba Mannheim® XL 1000 autoanalyzer was used in our laboratory for a blood examination.

Statistical analysis

Statistical analysis of our study was performed with the MedCalc Software program. Correlation and regression analyses, Bland-Altman analysis and conformity limits were determined with this programme. For the clinical confirmation of the study results, the error grid analysis developed in 1987 by Clarke et al. was used (Clarke et al., 1987). In this analysis, A, B, C, D and E zones are present and results falling into the A and B zones show clinical acceptability; results falling into the C, D and E zones show clinical unacceptability.

3. Results

In our study, 232 patient files were scanned. Since finger-prick glucose values of five patients were recorded as high and autoanalyzer results of 21 patients could not be obtained, our statistical values were calculated using 206 patients. The number of women enrolled in our study was 113 (54.9%) with an average age of 58.09±19.44 years, and the average age of the men was 61.26±16.14 years. There was no statistically significant difference between the average ages and sexes. In our study, a diabetes diagnosis for females was found to be significantly higher than for men (p=0.011). For our study, a comparison of glucose levels is provided in Table 1, and the correlation curve is shown in Fig.1. The regression analysis yielded the equation, y=0.9683+16.91. Fig. 2 shows that according to the Bland-Altman analysis, glucose values were mostly within conformity limits. Fig. 3 presents the results of the error grid analysis and shows that 92.2% of participants were in the A zone, 6.7% were in the B zone, and 0.97% were in the D zone.

Table 1. Comparison of blood glucose level autoanalyzer and capillary.

	N	BGMV	95 % CI	r
Autoanalyzer	206	207.21±134.22	0.9547-0.9736	0.9654
Capillary	206	196.52±133.82		

N: The number of participants, BGMV: Blood glucose mean values, r: Correlation coefficients

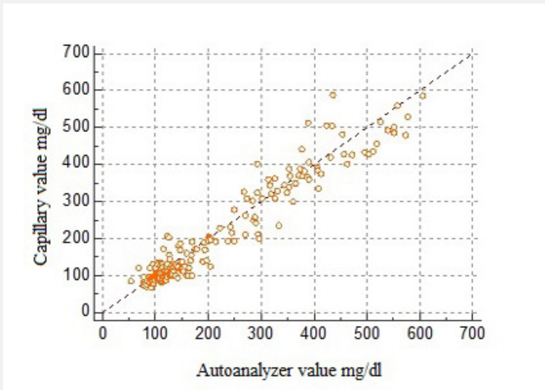

Fig. 1. Autoanalyzer-capillary correlation table.

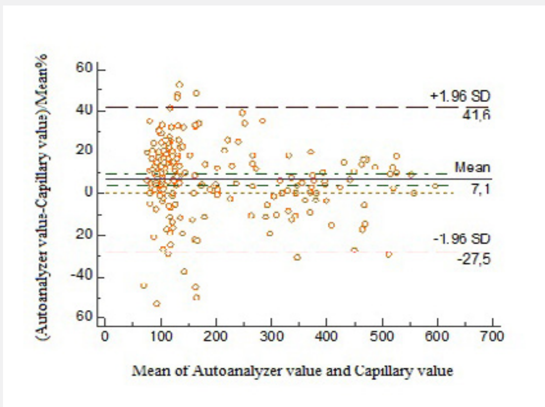

Fig. 2. Blant-Altman plot analysis.

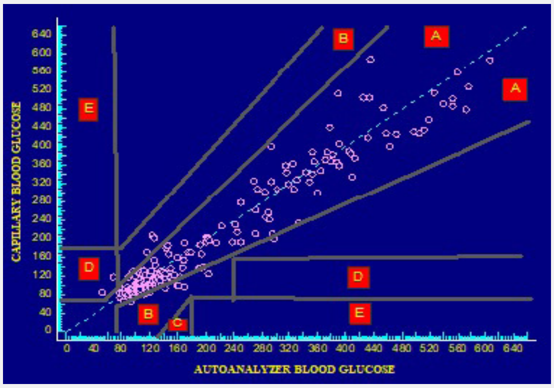

Fig. 3. Error grid analysis.

Limitations

Since our study is a retrospective file scanning study, our main constraint was the inability to standardise the collected samples. Capillary blood glucose levels detected from the patient files may be incorrectly recorded even with a low probability. While increased haematocrit levels reduced glucose measurements, decreased haematocrit levels result in higher glucose measurements. Although some new devices yield results by automatically correcting this issue, the bedside glucose measurement device that we use in our ED does not have this feature. In addition, the influence that the oxygenation state of the patient might have had on the glucometers and glucose measurement results and the presence of hyperlipidaemia could not be obtained from the files.

4. Discussion

In EDs, bedside capillary glucose measurement results are rapidly evaluated, and appropriate treatment is provided according to these results. The physician may look into the results of the autoanalyzer approximately an hour later and may evaluate the appropriateness of treatment. This period is too long for a patient in the ED. In addition, some patients require several additional glucose measurements to be performed until the results of the autoanalyzer are obtained. Therefore, it is important for bedside glucometers to yield relevant results. Furthermore, despite technological advances, autoanalyzer results are still obtained very late, and biochemical tools yielding rapid results are not found in EDs to a large extent. When we searched the literature related to this topic, we found a study by Boyd et al. in which they compared bedside glucose values in the ED (Boyd et al., 2005). The correlation coefficient between laboratory blood glucose values and capillary blood glucometer glucose levels was 0.97, and the correlation coefficient between venous blood glucometer glucose levels was 0.96. In the discussion section of this study, it states that 'although a good correlation is the norm between venous and capillary derived samples, caution must be exercised in accepting the results as equivalent or using either as substitutes for a laboratory blood glucose results.'(Boyd et al., 2005). In the study by Clarke et al. the correlation coefficient was 0.91, and regression analysis produced the equation, $y=0.92x + 20.09$ (Clarke et al., 1987). Yaraghi et al. measured glucose levels of comatose patients and found that the correlation coefficient between capillary and intravenous laboratory glucose measurements was 0.78 (Yaraghi et al., 2015). Nayeri et al. compared capillary blood glucose levels obtained with a glucometer to standard laboratory measurements (Nayeri et al., 2014). They found the sensitivity to be 83% and specificity to be 97.5% and stated that these values were acceptable. Thus, measurements performed with a glucometer were recommended as an appropriate diagnostic test (Nayeri et al., 2014).

In another study, Patel et al. compared glucose levels obtained by a glucometer and an autoanalyzer (Patel and Patel, 2015). They reported that measuring capillary blood glucose in diabetic patients and monitoring emergencies in non-diabetic patients are good alternatives to estimating venous plasma glucose (Patel and Patel, 2015). The study by Aral et al. compared the results obtained with a venous plasma autoanalyzer with those of capillary blood results, the correlation between the two methods was $r=0.969$ and regression was $y=0.910x+7.008$ (Aral et al., 2004). In the study by Chen et al., the regression was high, $y=0.79x+50$ and $r=0.77$ (Chen et al., 1998).

Other studies in the literature as well as our study report that measurements with a glucometer show a high correlation to a great extent, and it is reported to be an appropriate test. It is important to consider the clinical acceptability of the results that were found to be statistically positive. Aral et al. and Chen et al. stated this issue in their studies. They specified in their respective studies that having a high correlation is not sufficient for data to be evaluated clinically (Chen et al., 1998; Aral et al., 2004). Error grid analysis is being used for this purpose (Clarke et al., 1987). In error grid analysis, zones A and B specify clinical acceptability, whereas zones C, D and E specify unacceptability. In our study, 98.7% of measurements were found within the zones that are considered to be acceptable. In a study by Foss-Freitas et al., it was determined that a statistically significant difference was found between capillary and venous plasma values of non-glycaemic individuals during fasting (a period of 10-14 hours) (Foss-Freitas et al., 2010). However, no difference was found in diabetic patients, and capillary and venous plasma glucose levels were found to be statistically different in normoglycemic and diabetic patients (Foss-Freitas et al., 2010).

In an interesting study, Yang et al. compared venous and finger-prick glucose levels in healthy volunteers (Yang et al., 2012). In this study, fasting and postprandial glucose levels of 12 healthy volunteers were compared, and no significant difference was detected during fasting. However, a significant difference was detected in postprandial measurements, and capillary blood glucose values were found to be 35% higher than venous blood glucose levels. Although the intergroup correlation coefficient was r=0.875, venous blood glucose levels are specified as being better indicators clinically. Since the fasting states of patients were not questioned in the ED, misleading results may be obtained when compared with this study. This problem can be eliminated by conducting additional studies that are performed in patients whose fasting states are known (Yang et al., 2012). In the blood glucose monitoring systems evaluation performed by Freckmann et al. according to DIN EN ISO 15197 standards; seven of 34 systems could not completely satisfy the requirement for minimal accuracy according to ISO standards. In this study, they stated that faulty systems result in risky treatment decision making and that glucometers and test strips should be evaluated regularly and standardised to be in accordance with the quality standards (Freckmann et al., 2012).

In conclusion, all hospitals should check the glucometers that they use as standardised and should compare them with the results obtained with laboratory methods. Perhaps another important point is that a new biochemical autoanalyzer that can yield values very similar to reference values within a short period and allows rapid decision making at the clinical level needs to be developed.

Conflict of interest

The author declares that there is no conflict of interest.

Ethical approval

The study was approved by the Ethics Committee of İzmir Katip Çelebi University Non-interventional Clinical Studies Institutionel Review Board (Date: 30.12.2015, No: 251). The study was conducted in accordance with the principles of the Declaration of Helsinki.

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