COMPARISION BETWEEN BED SIDE TESTING OF BLOOD GLUCOSE BY GLUCOMETER Vs CENTRALIZED TESTING IN A TERTIARY CARE HOSPITAL

Ayaz Baig*, Imran Siddiqui,* Abdul Jabbar, Syed Iqbal Azam,*** Salman Sabir,*** Shahryar Alam,* Farooq Ghani***

***Section of Chemical Pathology, Department of Pathology & Microbiology, ** Section of Endocrinology, Department of Medicine, ***Department of Community Health Sciences, Aga Khan University Karachi**

Background: To determine the accuracy, turnaround time and cost effectiveness of bedside monitoring of blood glucose levels by non–laboratory health care workers and centralized testing of blood glucose by automated analyzer in a tertiary care hospital. **Methods:** The study was conducted in Section of Chemical Pathology, Department of Pathology and Microbiology and Section of Endocrinology Department of Medicine, Aga Khan University and Hospital Karachi, from April 2005 to March 2006.One hundred and ten patients were included in the study. The blood glucose levels were analyzed on glucometer (Precision Abbott) by finger stick, using Biosensor Technology. At the same time venous blood was obtained to analyze glucose in clinical laboratory on automated analyzer (SYNCHRON CX7) by glucose oxidase method. **Results:** We observed good correlation between bed side glucometer and laboratory automated analyzer for glucose values between 3.3 mmol/L (60 mg/dl) and 16.7 (300 mg/dl). A significant difference was observed for glucose values less than 3.3 mmol/L (p=0.002) and glucose values more than 16.67 mmol/l (p= 0.049). Mean Turnaround time for glucometer and automated analyzer were 0.08 hours and 2.49 hours respectively. The cost of glucose testing with glucometer was 48.8% lower than centralized lab based testing. **Conclusion:** Bedside glucometer testing, though less expensive does not have good accuracy in acutely ill patient with either very high or very low blood glucose levels.

Key words: Bed side testing; Glucometer; Centralized glucose testing

INTRODUCTION

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 [1].

Various mechanisms have been used to meet these clinical needs, e.g. establishment of specialized "Stat" laboratories, pneumatic tube systems to improve specimen transport to centralized laboratories and use of point of care testing. A number of synonyms for near patient testing and testing sites have been used in medical literature, including alternate site testing, point of care testing, bedside testing and physician's office laboratory.[2]
Point-of-care testing or near patient testing is defined as "Diagnostic Testing that is performed near or at the site of patient care[3]. Major advantages of near patient testing are the time saving that could facilitate important diagnostics and management decisions[4].

Most of the benefits for the physicians, nurses, patients and administration 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[3].

The dynamic equilibrium between medical utility, technological capabilities and cost determines whether laboratory testing is conducted in central laboratories or at distributed sites[5].

Accuracy is the ability of a test to produce results close to the best available measure[6]. Turn around time (TAT) is a complex process that begins with the phycisician's initiation of a laboratory order, continues with the acquisition of the appropriate specimen, proceeds with the actual analysis time, and concludes with the transmission of the results to the physician[7]. To determine accuracy, turn around time and cost effectiveness, we performed blood glucose levels in the central laboratory on automated analyzer and at bedside by non-laboratory health care professionals with glucometer.

Glucometer 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[8].

Point of care testing is not widely used in hospitals; there are only few places like intensive care units, emergency departments where arterial blood gases and glucose testing is performed to know the current status and to provide immediate care to the patient. In various hospitals and out patient clinics, glucometers 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 favorably to the much longer time experienced with centralized testing.

Keeping in mind their widespread utility we conducted the study to compare the analytical performance, turn around times and cost effectiveness of the two glucose testing modalities.

MATERIAL & METHODS

This study was conducted in the chemical pathology section of Department of Pathology and Microbiology and the endocrinology section of Department of Medicine, Aga Khan University and Hospital, Karachi, from April 2005 to March 2006. One hundred and ten patients were tested simultaneously with glucometer and an automated analyzer in the clinical laboratory. Information regarding age, gender, time of blood glucose testing, and glucose result was gathered on a pre-designed proforma. Sodium fluoride (NaF) was used as preservative in all our samples.

The blood glucose levels were analyzed on glucometer (Precision, Abbott) by finger stick, using a biosensor technology. A drop of blood was applied to the electrode/strip (provided by the manufacturer, having lot number and expiry date) by a registered nurse and the reading was noted on digital window of glucometer. There are three electrodes in the Precision QID electrochemical strips (active, background compensation, and reference electrode). The background compensation electrode lacks glucose oxidase but measures the signal from potentially interfering substances. This nonspecific signal is used to modify the signal produced by the primary active electrode. The glucose in the blood combines with the chemicals on the electrodes to produce very small electrical currents. The sensor measures these currents and displays results in digits. At the same time three milliliter (3ml) of blood was obtained by venepuncture in a tube containing fluoride and oxalate as preservative. The tube was marked for identification and transported to clinical laboratory, section of chemical pathology. Plasma was separated by centrifugation, at a speed of three thousand rounds per minutes for a period of five minutes with a relative centrifugal force of 1400 (rcf) and was analyzed on automated analyzer (SYNCHRON CX7) by glucose oxidase method.

Statistical analysis was done using SPSS (version 13.0) software. Simple Correlation Coefficient and Simple Linear Regression was used to see the association and relation between the two methods. Data was analyzed by dividing patients into three groups based upon their blood glucose values (Less than 3.3mmol/L, 3.3-16.6 mmol/L and more than 16.6 mmol/L) obtained by standardized automated testing in the e laboratory.

RESULTS

A total of 110 patients were enrolled in the study. More than half (57.3%) of them were males. The average age of patients was 56.85 years (ranged between 18 to 93 years; Median age = 58.5 years) (Table 1).

A significant difference was observed between the two glucose testing methods for patients whose blood glucose values were less than 3.33 mmol/L (Mean difference = -0.60; 95% C.I. for the difference = -0.86, -0.34; *p-value*=0.002) or above 16.67 mmol/L. (Mean difference = 3.09; 95% C.I. for the difference = 0, 6.19; *p-value* = 0.049). It was observed that glucometer readings were higher as compared to centralized glucose readings for centralized glucose levels below 3.33 mmol/L and lower for centralized glucose readings above 16.67 mmol/L.

No significant difference was observed between centralized glucose reading and glucose testing using glucometer for centralized glucose levels in the range of 3.33 to 16.67 mmol/L. (Mean difference = -0.02; 95% C.I. for the difference = -0.32,0.28, ; *p value* =0.893) Table 2. Linear regression analysis showed good correlation between the two methods ((r^2 = 0.82) as shown in Figure 1. The model is: Glucose Centralized reading (estimated) = 1.01 + (0.88) (Glucometer reading). It means that one mmol/L change in Glucometer reading will result in 0.88 mmol/L changes in Glucose Centralized reading.

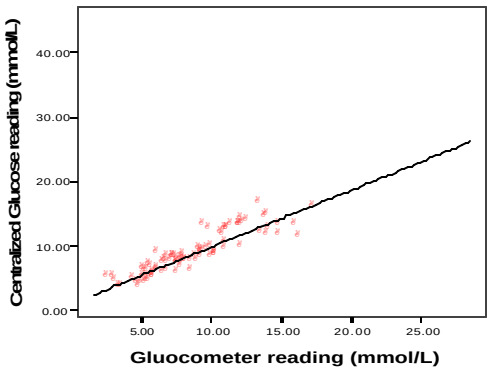

Figure 1. Scatter Plot and Estimated Regression Line between Centralized Glucose Test readings and Glucometer readings[1]

[1] Only for observations, where centralized glucose test readings were between 3.3 and 16.6 mmol/L

Descriptive statistics

Table 1. Percentage and Mean Distribution of demographic and blood glucose Characteristics

Characteristics	*Number*	*(%)*
Age (years):		
<30 years	6	(5.5)
30 – 39 years	5	(4.5)
40 – 59 years	46	(41.8)
60 years & above	53	(48.2)
Average age (SD)	56.85	(14.58)
Gender:		
Male	63	(57.3)
Female	47	(42.7)
Blood Sample:		
Fasting samples	54	(49.1)
Random Samples	56	(50.9)
Characteristic of blood glucose	*Mean (95% C.I. for mean)*	
Glucose Reading (mmol/L) using:		
Glucometer	10.02	(8.95,11.09)
Glucose Reading (mmol/L) using:		
Centralized using Automated analyzer	10.36	(9.05,11.67)
Difference in glucose level (mmol/L):		
Glucometer vs. Centralized	0.34	(-0.13, 0.82)
Average turn around time of testing using Centralized (in hours):	2.49	(2.22, 2.77)

Table 2. Distribution of the mean difference of centralized and glucometer readings at different cut offs of centralized glucose level with 95% confidence interval for mean difference

Glucose Levels mmol/L	**Glucometer Mean (SD)**	**Centralized Mean (SD)**	**Mean Difference (SD)**	**95% C.I. for Mean Difference**	**p-value**
<3.3	2.57 (0.75)	1.97 (0.72)	-0.60 (0.25)	-0.86, -0.34	0.002
3.3-16.67	8.71 (3.32)	8.69 (3.23)	-0.02 (1.46)	-0.32, 0.28	0.893
>16.67	21.59 (3.25)	24.69 (7.60)	3.10 (1.43)	0+, 6.19	0.049

Average TAT for centralized glucose testing was 2.49 hours (Table I). Mean time for glucose testing with glucometer was 0.08 hours (5 minutes). The cost of supplies for glucometer was 57% higher than reagent cost for laboratory based testing. However, the total cost glucometer test was 48.8 % lower than lab based test owing to the additional cost incurred by the lab such as space, manpower and utilities.

DISCUSSION

Bedside blood glucose testing using reagent-impregnated strips and simple reflectance meters has been enthusiastically accepted as quick and simple means to monitor blood glucose levels[9]. The importance of the self-monitoring of blood glucose using home blood glucose meters has prompted numerous reports in scientific literature regarding the statistical and clinical accuracy of these devices[10].

The availability of sophisticated dry and wet chemistry systems that offer a sizeable menu of laboratory tests has made it possible for laboratory tests to be done out side the central clinical laboratory[4].

The electro-chemical based glucometer systems have glucose catalytic enzymes, electron mediators and electrodes in strip. During glucose oxidation, the electrochemical system measures the current, the magnitude of which correlates with glucose concentration in the sample[11]. Studies have been done to compare results between glucometer of different manufacturers but we are not aware of any study which compared glucometer and laboratory based automated testing over a large range of glucose levels that evaluated the accuracy, turn around time and cost effectiveness of these devices. Studies in physician's office laboratories in the United States have shown a large variability in results obtained with physician office analyzers[4].

There was good correlation between two methods in the range between 3.3mmol/L and 16.67 mmol/L, which suggests that glucose values falling in non-critical range can be safely used when making decisions only by glucometers (Fig1). This also highlights that technique used by non-laboratory health care workers was satisfactory. It has been shown that most glucometers are inaccurate at very high or very low glucose concentrations and certain variables like haematocrit, altitude, environmental temperature or humidity and hypoxia may affect the result with bedside testing[12]. Finger stick glucose testing does not accurately represent venous glucose

levels in severely hypotensive patients and an error in clinical management can be made[13]. In our study glucometer readings were higher in patients having glucose values below 3.33mmol/L in relation to centralized glucose testing. Centralized glucose values were higher in patients who had glucose levels higher than 16.67mmol/L when compared with glucometer.

We observed that few patients were over estimated for hypoglycemia when tested with glucometer. This overestimation could have detrimental consequences because glucose values were lower in these patients when tested simultaneously on automated system. Glucose values were underestimated with glucometer in higher range when compared with centralized testing. Four patients whose initial glucose values were on glucometer were reported as 22.7, 28.5, 24.8 and 21.8 mmol/L eventually turned out be much higher on lab based analyzers, i.e. 31.7, 45.2, 31.7 and 29.9 mmol/L respectively. Treatment of these patients was intensified and potential complications were averted. These findings suggest that at very low and high glucose readings, glucometer can either over or underestimate glucose results so it is good practice to confirm low and high glucometer readings with centralized laboratory before giving any treatment. Centralized blood glucose has the added advantage of internal and external quality control as well. Our results for internal quality control, using Levy Jennings Charts were within ±2SD. Calibration was performed daily and three levels of controls (L1, L2, L3) were run on SYNCHRON CX-7. External quality assurance was evaluated by Bio-Rad (External Quality Assurance Service, EQAS, a United States based external quality control agency) were also acceptable. Internal quality control for glucometer was also used; low and high controls were run after every fifteen days and were recorded. This could be the reason for good agreement between bedside testing and centralized glucose testing. Glucometer we used in study measures plasma glucose. This was in the light of Clinical and Laboratory Standards Institute guidelines for point-of- care blood glucose testing published in 2002, which recommends that institutions reporting plasma glucose results from instruments in clinical laboratory should use point-of-care devices that report plasma-equivalent results[15]. Nanji et al showed in their study that those systems having least number of steps in their operation are most likely to produce results in hands of non-technical persons. There are few responsibilities of non health care professionals involved in bed side monitoring; they should know specimen and instrument handling, concept of accuracy, trouble shootings, quality control, preventive measures and corrective action for the instrument.

TAT requires a complete review of factors starting from inception of the order to the complete result that is available to the clinician or to the related person. In our study, mean TAT for centralized testing was 2.49 hours, minimum reporting time was 0.65hours and maximum reporting time was 9.3 hours. Mean turnaround time for bedside testing was 0.08 hours (5minutes). Reporting time for eight patients was more than 4 hours. This delay in reporting could be dangerous in term of their therapeutic management. The reason for prolong reporting was pre-analytical factor as delay was acquiring the sample in laboratory by the phlebotomist.

Studies in large tertiary care teaching hospital[14]and in smaller community hospital[15] have shown that the major contributors to prolonged laboratory TAT are pre-analytical factors, primarily delays in transmission of the physician's order and delays in acquiring the specimen by the laboratory. Similar observations were reported by Saxena and Wong[16] at a large emergency department.

Analysis time was only a small fraction of total TAT. Post-analytical time (i.e., the time to verify the results and transmit them to the clinician) was minimal as clinical laboratory is connected with wards and emergency department by Laboratory Information system and Hospital Information System. With bedside testing, data is available very quickly but do not get into permanent record. This data loss may be critical in reviewing the course of complex, critically sick patients.

Cost determination for both bedside and centralized laboratory testing included labor cost, quality control, reagents, technologists/consultants time, disposables (tips, syringes, and tubes), power expense, house keeping and for laboratory computer systems were considered. Jerome and Keefner[7] suggested that point of care testing is a more expensive way to deliver rapid laboratory service, however in another study Zaloga[17]and coworkers stated that a point of care testing device appears to be cost effective.

CONCLUSION

Finding in our study suggest that very low and high glucose values with glucometer do not accurately reflect actual plasma glucose levels. In order to make critical decisions at these levels, plasma glucose should be confirmed with centralized laboratory based methods. The bedside glucose testing with glucometer is a simple, rapid, cost effective method for glucose monitoring. On the other hand centralized glucose testing despite having more

turnaround time and high financial impact is still more reliable and accepted method for diagnosis and management of the patient in acute care setting.

REFERENCES

1. Jacobs E, Vadasdi E, Sarkozi L, Colman N. Analytical evaluation of i-STAT Portable Clinical Analyzer and use by nonlaboratory health-care professionals.Clin Chem 1993;39(6):1069-74.
2. Friedman BA, Mitchell W. Integrating information from decentralized laboratory testing sites. The creation of a value-added network. Am J Clin Pathol 1993; 99:637-42.
3. Ellis Jacob. Point of care (near-patient) testing. Kaplan LA, Pesce AJ, Kazmierezak SC.Clinical Chemistry 3rd ed: New York: Mosby; 1996.p.313-22.
4. Nanji AA, Poon R, Hinberg I. Near-patient testing. Quality of laboratory test results obtained by non-technical personnel in a decentralized setting. Am J Clin Pathol 1998; 89(6):797-801.
5. Winkelman JW, Wybenga DR, Tanasijevic MJ. The fiscal consequences of central vs distributed testing of glucose. Clin Chem 1994; 40(8):1628-30.
6. Dillion AE, Menard MK, Rust P, Newman RB, VanDorsten JP. Glucometer analysis of one-hour glucose challenge samples. Am J Obstet Gynecol 1997; 177(5):1120-23.
7. Nosanchuk JS, Keefner R. Cost analysis of point-of-care laboratory testing in a community hospital. Am J Clin Pathol 1995; 103(2):240-43.
8. Hamid MH, Chishti AL, Maqbool S. Clinical utility and accuracy of a blood glucose meter for detection of neonatal hypoglycemia.J Coll Physicians Surg Pak 2004; 14(4):225-28
9. Greendyke RM. Cost analysis. Bedside glucose testing. Am J Clin Pathol 1992; 97(1):106-7.
10. Trajanoski Z, Brunner GA, Gfrerer RJ, Wach P, Pieber TR. Accuracy of home blood glucose meters during hypoglycemia. Diabetes Care 1996; 19(12):1412-15.
11. Tang Z, Du X, Louie RF, Kost GJ. Effects of drugs on glucose measurements with handheld glucose meters and portable glucose analyzer. Am J Clin Pathol 2000; 113(1):75-86.
12. Sacks DB, Bruns DE, Goldstein DE, Maclaren NK, McDonald JM, Parrott M. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Clin Chem 2002; 48(3):436-72.
13. Atkin SH, Dasmahapatra A, Jaker MA, Chorost MI, Reddy S. Fingerstick glucose determination in shock. Ann Intern Med 1991; 114(12):1020-24.
14. Nosanchuk JS, Salvatore JD. Improved pneumatic tube system shortens stat turnaround time. Lab Med 1977; 8:21-25.
15. Nosanchuk JS, Stull R, Keefner R. The effect of substitution of plasma for serum on chemistry turnaround time. Lab Med 1991; 22: 465-69.
16. Saxena S, Wong ET. Does the emergency department need a dedicated stat laboratory? Continuous quality improvement as a management tool for the clinical laboratory. Am J Clin Pathol 1993; 100(6):606-10.
17. Zaloga GP, Hill TR, Strickland RA, Kennedy D, Visser M, Ford K et al. Bed side blood gas and electrolyte monitoring in critically ill patients. Crit Care Med 1989; 17(9): 920-25.

Address of Correspondence: Dr. Ayaz Baig, Department of Pathology & Microbiology, The Aga Khan University Hospital, Stadium Road, Karachi 74800, Pakistan. Ph: +92 21-4930051, Ext: 4530, 1564
E-mail: ayaz.baig@aku.edu