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ORIGINAL ARTICLE

Comparison of Point-of-Care Hemoglobin A1c testing with Central Laboratory methods for screening and monitoring Diabetes Mellitus in Resource-Constrained Settings

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ABSTRACT

Background: Hemoglobin A1C (HbA1c) is often used for evaluating long term glycemic control in patients suffering from diabetes. In resource-constrained settings, the availability and accessibility of diagnostic facilities are often limited. Point-of-care (POC) testing for HbA1c has emerged as a potential solution to overcome these barriers

Methodology: A cross-sectional study conducted at Bahawal Victoria Hospital in Bahawalpur from May 2022 to October 2022 for a period of six months following ethical review committee permission. This research includes 173 subjects. On the same visit, blood samples were taken for HBA1C measurement using both a centralized laboratory approach (Turbidimetric Inhibition Immunoassay, TINIA) and a point-of-care testing (POCT) method (Biohermes A1C EZ 2.0). Patients were placed into three groups based on their HBA1C levels: Group A (less than 5.6%), Group B (5.6%-6.7%), and Group C (more than 6.7%). Group C was divided into two categories: diabetics with adequate glycemic control (HBA1C < 7%) and diabetics with poor glycemic control (HBAIC > 7%). Data was analyzed by using SPSS version 24.0. P-values of ≤0.05 will be considered statistically significant

Results: The result has shown that study sample consisted of 173 individuals with a mean age of 51.2 years (±SD 5.4) with 98 males (56.64%) and 75 females (43.36%). The participants had an average BMI of 28.3 (±SD 5.6). Group A has 32, Group B has 44, Group C with good control has 52 and Group C with poor control has 45 participants. The mean TINIA measurement for these groups were 5.1 ± 1.13, 6.0 ± 0.93, 6.8 ± 1.40 and 10.3 ± 2.31 respectively. While the POCT results for these groups A, B,C with good and poor control were 5.2 ± 0.41, 6.1 ± 0.23, 6.7 ± 0.83 and 10.9 ± 1.78 respectively. The comparison results of these methods using the Spearman test (non-parametric data), a correlation coefficient (r) of 0.75, p<0.001 was obtained.

Conclusion: The findings of this study support the integration of point-of-care HbA1c testing into diabetes screening and monitoring programs in resource-constrained settings, offering a pragmatic approach to contain the growing burden of diabetes in Pakistan.

Keywords: Hemoglobin, Immunoassay, HbA1c, Diabetes, Correlation, Coefficient.

INTRODUCTION

Diabetes mellitus is a chronic, complex metabolic disorder characterized by long-term raised blood glucose levels that can have serious, long-term complications, and result in high morbidity and mortality. Either insulin action, secretion or both[1]. Worldwide, diabetes prevalence is expected to rise from 9.3% in 2019 to 10.9% in 2045, and higher rates are expected in high income and metropolitan areas[2]. The disease is also a major worldwide chronic illness burden in aging societies with 19.3% of people aged between 65 and 99 years old having diabetes in 2019[3]. Hemoglobin A1C (HbA1c) is one of the many biomarkers used to evaluate glycemic management of diabetes patients over a long period of time. The HbA1c test, an important glycemic marker for diabetes mellitus, reflects the mean blood glucose level of the previous two to three months. In resource constrained settings, the availability and accessibility of diagnostic facilities is limited. HbA1c testing at the point of care (POC) has been developed as a potential solution to these barriers[4].

Data from several health organizations such as American Diabetes Association (ADA) has established the diagnostic criteria for diabetes with the use of HbA1c levels. The ADA also states that if your HbA1c is 6.5% or higher, then you are diagnosed with diabetes[5]. If symptoms of hyperglycemia are not present, repeating the test on a subsequent day will confirm this diagnosis. HbA1c testing is also used as a screening tool in people considered at high risk of developing diabetes, including those who are obese, have a family history of diabetes or are of a particular ethnic origin[6]. If a screening test shows a higher-than-normal HbA1c reading, it may indicate the need for more blood glucose testing and monitoring. People with diabetes should have their HbA1c levels checked from time to time to monitor long term glycemic control and guide treatment choices. Low HbA1c values are connected with a lower risk of diabetic complications[7].

HbA1c testing is beneficial over other methods for detecting diabetes mellitus. Here are several major advantages. HbA1c measures average blood glucose over the previous 2 to 3 months compared with tests like fasting blood glucose or oral glucose tolerance tests, which provide a snapshot of glucose levels at a single point in time[8]. HbA1c testing differs from other fasting blood glucose testing in that it does not require fasting by patients prior to the test, which makes it more convenient for both patients and healthcare providers. This eliminates the need for patients to reserve appointments to have fasting blood drawn, which can be both time consuming and lead to missed appointments[9]. HbA1c testing is a stable test for long term glycemic control and it is reliable even in those with variable daily glucose levels.

A comparison of point of care (POC) Hemoglobin A1c (HbA1c) testing with central laboratory methods includes accuracy, precision, reliability, feasibility and cost effectiveness. Typically, central laboratory methods include high performance liquid chromatography (HPLC) or immunoassay techniques[13]. They are well established and standardized with high accuracy and precision. HbA1c POC (point of care) testing devices differ in technology and performance. Some POC devices have comparable accuracy to central laboratory methods while others may have reduced precision and higher variability[14]. All of this is done in a central lab, controlled environments, by trained technicians to generate consistent and reliable results. Since POC testing may be more susceptible to environmental factors, user

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variability and device calibration issues, reliability is likely to be more of a concern in non clinical settings.

Specialized equipment and trained personnel, and centralized facilities are required for central laboratory testing, which may limit this to remote or resource constrained settings. POC HbA1c testing has been advantageous in that it is accessible, especially in primary care clinics, community health centers, and remote areas that lack or are not practical for centralized laboratory facilities. Typically, sample transportation, processing, and batch testing result in longer turnaround times from central laboratory testing. Rapid POC HbA1c testing allows immediate clinical decision making as well as patient counseling during the same visit[15–18]. The costs associated with equipment, infrastructure, maintenance and personnel are higher for central laboratory testing. The POC HbA1c testing devices vary in cost but provide reduced turnaround time, decreased reliance on centralized facilities, and potential avoidance of follow up visits for test results. Typically, central laboratories follow strict quality control measures such as proficiency testing, calibration and validation. In decentralized healthcare settings, POC HbA1c testing requires robust quality control and assurance processes to achieve accuracy, reliability, and regulatory compliance[19-21].

MATERIAL AND METHODS

A cross-sectional study was done at Bahawal Victoria hospital Bahawalpur from May 2022 to October 2022 for a period of 6 months with permission of ethical review committee. This research included all patients hospitalized in Islam Teaching Hospital, Sialkot in the specified timeframe and vetted for inclusion. A specific criterion for inclusion and exclusion was developed. Patients aged 18 years and older with diabetes mellitus diagnosis or suspected diabetes by clinical signs such as polyuria, polydipsia and unexplained weight loss were included in this study. The American Disease Association (ADA) standards recommend that HBA1c should not be used in the patients with disease in which increased red blood cell turnover occurs[21]. Therefore, people with diagnosed diseases such as hemolytic anemia or sickle cell disease, hemophilia, thalassemia, hereditary spherocytosis, chronic hepatic or renal disease, iron deficiency or hemolytic anemia were not included in the research. Also, those who had had a blood transfusion or chemotherapy within the previous three weeks were excluded. Patients with the history of alcoholism or substance misuse, since such patients may affect glucose metabolism and HbA1c levels. Patients who are pregnant, as pregnancy can affect HbA1c levels. Patients with known contraindications to venipuncture or finger stick blood sampling procedures and with unstable medical conditions requiring immediate intervention or hospitalization were also excluded.

Following screening of 230 individuals, 173 patients met the study's predetermined criteria and were added to the sample. Informed consent was obtained after the chosen sample was fully informed about the stages and process involved in this investigation, including any possible risks and benefits. All of the patients' clinical and biographical details, including age, gender, ethnicity, socioeconomic position, clinical presentation, and symptom duration, were recorded. Vital signs including blood pressure, pulse and temperature of every participant were noted. Blood samples were collected for measuring HBA1C levels through centralized laboratory method and point of care method on the same visit. Capillary blood was collected by trained health care professional via finger prick and it was analyzed by using POCT HbA1c analyzer (Biohermes A1C EZ 2.0). The results obtained were noted for each participant. For the purpose of HBA1C measurement through central standardized laboratory method, TINIA (Turbidimetric Inhibition Immunoassay) was used. 5 milliliter of venous blood samples were collected from each patient and the sample were stored in EDTA vials. These samples were transported to pathology laboratory in the Islamic teaching hospital.

All the samples were stored at +4°C temperature and all the assays were performed by trained laboratory technologist. The results obtained were noted for each participant. According to the HBA1C levels the patients were divided into three groups labelled as Group A with HBA1C levels < 5.6%, Group B with HBA1C levels 5.6%-6.7% and Group C with HBA1C levels > 6.7%. Group A consisted to people with normal HBA1C levels, Group B consisted of diaspora with impaired glycemic control and Group C was formed by participants suffering from diabetes mellitus. The Group C was further broken down into two categories that includes diabetics with good glycemic control (HBA1C<7%) and diabetics with poor glycemic control (HBAIC>7%). Data was entered and analyzed to compare the sensitivity and specificity of POCT and TINIA assay for measure of HBA1C SPSS (Statistical Package for the Social Sciences) version 24. It was presented as mean, standard deviation, and percentages. P-values of ≤0.05 were considered statistically significant. The findings were interpreted in the context of the study objectives and existing literature.

RESULT

The study sample consisted of 173 individuals with a mean age of 51.2 years (±SD 5.4). The gender distribution within the sample comprised 98 males (56.64%) and 75 females (43.36%). The participants had an average BMI of 28.3 (±SD 5.6). Hypertension was prevalent among 69 individuals (39.88%), while 71 participants (41.04%) reported a history of smoking (Table 1, Figure 2). These demographic and health characteristics provide a snapshot of the study population, reflecting a middle-aged cohort with a slight male predominance and a notable prevalence of hypertension and smoking history. The study involved four distinct groups categorized based on their HbA1c levels: Group A, Group B, Group C, and Poor Control. Group A comprised individuals with HbA1c levels below 5.6%, consisting of 32 participants. For this group, the mean TURBIDIMETRIC INHIBITION IMMUNOASSAY (TINIA) measurement was 5.1 ± 1.13, while the POINT OF CARE HBA1C TESTING (POCT) measurement averaged at 5.2 ± 0.41.Moving to Group B, encompassing individuals with HbA1c levels ranging from below 5.6% to 6.7%, there were 44 participants. In this group, the mean TINIA measurement was 6.0 ± 0.93, slightly higher than in Group A, while the mean POCT measurement was 6.1 ± 0.23.Group C, denoted as "Good Control," included 52 participants with HbA1c levels below 7%. In this group, both TINIA and POCT measurements increased further, with mean values of 6.8 ± 1.40 and 6.7 ± 0.83, respectively. Lastly, the Poor Control group consisted of 45 individuals with HbA1c levels exceeding 7%. Here, both TINIA and POCT measurements showed considerable elevation, with mean values of 10.3 ± 2.31 and 10.9 ± 1.78, respectively (Table 2, Figure 2).

Table 1: Demographic characteristics of population under study

Variable	Study sample (n=173)
Age (years) (mean ± SD)	51.2 ± 5.4
Gender Male Female	 98 (56.64 %) 75 (43.35 %)
BMI (mean ± SD)	28.3 ± 5.6
Hypertension	69 (39.88%)
History of Smoking	71 (41.04%)

These results demonstrate how HbA1c readings change throughout groups and demonstrate how well TINIA and POCT work to identify and evaluate glycemic control in people with a range of HbA1c levels.A correlation study was carried out to compare the outcomes of the POCT and TINIA techniques. The POCT technique results were represented on the y-axis, while the TINIA data were put on the x-axis. The findings demonstrated a strong positive association between the two examined approaches. When comparing these approaches with non-parametric data using the Spearman test, a correlation coefficient (r) of 0.75, p<0.001, was found.

The findings also indicate that Point of Care Testing (POCT) is more economical than Turbidimetric Inhibition Immunoassay

(TINIA). On the other hand, the results of HBA1C via POCT can be obtained within minutes, whereas the TINIA provided results within 24 hours. However, compared to a Turbidimetric Inhibition Immunoassay (TINIA), a Point of Care Testing (POCT) device can do the test with a smaller quantity of sample, only 10 µl, instead of 1 ml. Unlike in TINIA, which is performed through meticulous phlebotomy procedures and the need to obtain venous blood, POCT is very conveniently performed by use of a sample from a simple finger prick. This feature greatly facilitates the practicality and accessibility of the POCT and makes it possible to implement it in clinical settings.

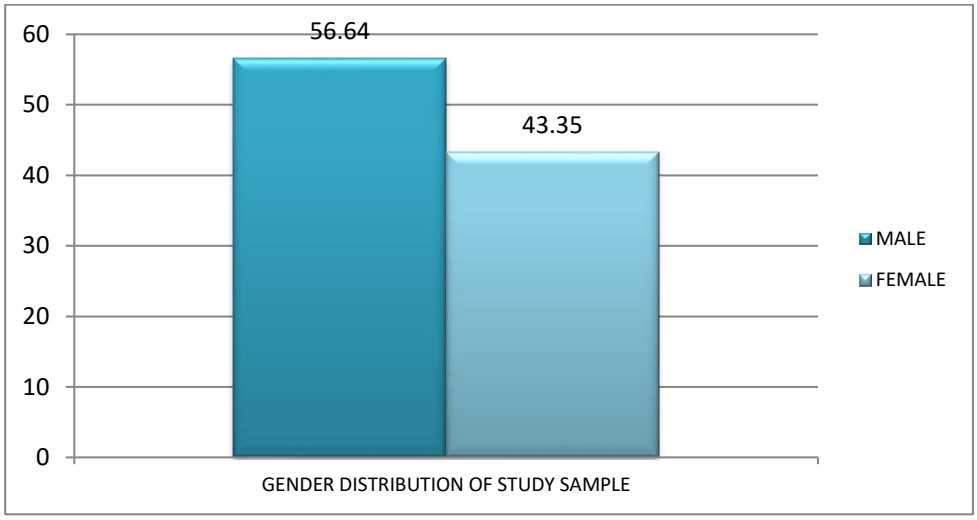

Figure 1: Gender distribution of study population

Table 2: Comparative analysis of results of POCT and TINIA methods

Method	Group A (HBA1C<5.6%) N=32	Group B HBA1C<5.6%-6.7%) N=44	Group C	
			Good Control (HBA1C<7%) N=52	Poor Control (HBA1C>7%) N=45
Turbidimetric Inhibition Immunoassay (TINIA)	5.1 ± 1.13	6.0 ± 0.93	6.8 ± 1.40	10.3 ± 2.31
Point of Care HBA1C testing (POCT)	5.2 ± 0.41	6.1 ± 0.23	6.7 ± 0.83	10.9 ± 1.78

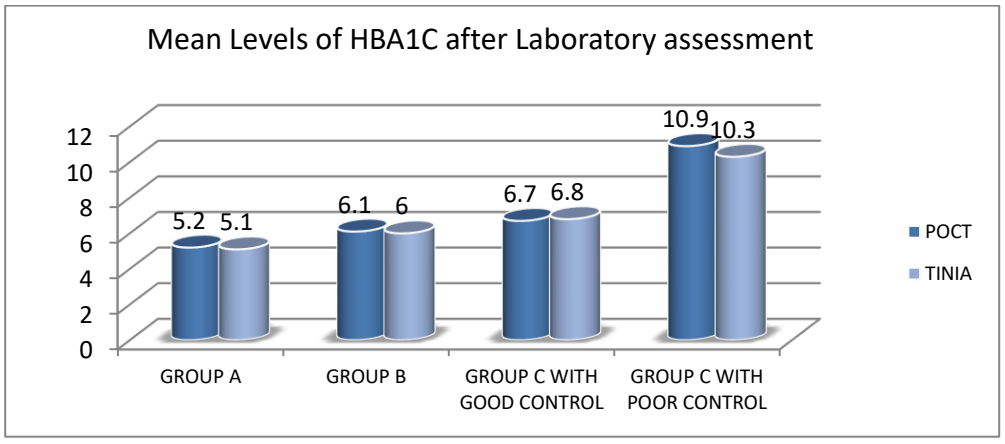

Figure 2: Mean levels of HBA1C after laboratory testing

DISCUSSION

Two major methods used for the diagnosis and treatment of diabetes mellitus are the use of fasting blood glucose levels (FBG) and Hemoglobin A1c (HbA1c). FBG measurements are tests of blood glucose following an overnight fast — usually the individual's glycemic status at a given point in time. This method gives a snapshot of the current blood glucose level (it is simple and relatively cheap[21,22]. Although, FBG can be influenced by factors such as recent food intake or stress and may result in variability in results. On the other hand, HbA1c measures average blood glucose levels over the preceding two to three months and represents a bigger picture of glycemic control. It is not affected by short term fluctuations and does not need fasting, and it is convenient and easy to administer. However, HbA1c results can be affected by factors, including hemoglobin variants, or certain medical conditions which may affect the accuracy of results[23]. Both FBG and HbA1c play critical roles in diabetes diagnosis and management, each with its distinct advantages and limitations. FBG provides immediate insight of the current glycemic status and is appropriate for initial diabetes screening. On the other hand

HbA1c gives a long term picture of glycemic control for assessment of treatment efficacy and risk stratification of complications. Both tests can be combined to provide a comprehensive evaluation of diabetes management, using the information to tailor interventions and monitoring[24]. Nevertheless, it is important to acknowledge the inherent variability and inherent limitations of each method, and to use judiciously the interpretation and clinical decision making.

Different ways of measuring the glycated hemoglobin (HbA1c) are available. It is usually determined by using HPLC or immunoassay methods. In HPLC, HbA1c is quantified from its retention time following chromatographic separation of the blood sample. The use of antibodies to HbA1c specific to HbA1c in immunoassay methods for the detection and quantification of HbA1c in the blood sample. The use of these methods provides high precision and accuracy to allow for accurate assessment of long-term glycemic control. A new technique of point of care HBA1C testing has emerged. POC HbA1c testing is a clinically significant, cost effective, reproducible instrument for the management of diabetes in resource constrained settings, for use in the identification of high-risk patients and facilitating referrals to secondary diabetic services[25].

Results from Turbidimetric Inhibition Immunoassay (TINIA) and Point of Care HbA1c Testing (POCT) are presented across groups classified by HbA1c levels. On analysis, it can be seen that both TINIA and POCT are giving comparable results on each of the mentioned groups. The measurements of TINIA and POCT are in close agreement over the HbA1c range from people with HbA1c below 5.6% to people with poor control (HbA1c > 7%).

The agreement in results indicates that POCT may provide a viable alternative to TINIA, especially in settings where laboratory facilities are resource constrained. POCT is capable of delivering reliable HbA1c assessments and thus may be useful for screening and diabetes monitoring in such settings[26]. POCT offers comparable results to TINIA and is a practical and efficient alternative for healthcare practitioners interested in accurately assessing HbA1c levels so as to undertake timely interventions and improve patient outcomes in resource limited environments.

Many studies have shown the usefulness and advantages of encouraging the use of POCT in resource limited settings. An Indonesian study suggests that POCT-HbA1c can replace standard diagnostic laboratory HbA1c measurement for diabetes screening and follow up with a sensitivity of 97.83% and specificity of 77.42%[27]. POCT of HbA1c may enable more timely diabetes management action in patients with worsening illness and improve the population health driven HbA1c testing adherence during primary care office visits. Recent advances in electrochemical detection and point-of-care (PoC) devices for HbA1c quantification show promise for improved speed, accuracy, and cost-effectiveness[28].

The results from this study indicate that point of care hemoglobin A1c (HbA1c) testing is equivalent to the central laboratory method and may serve as a screening and monitoring tool for diabetes mellitus in resource constrained settings. Results from this study showed that the point of care testing is advantageous as it provides rapid turnaround times, convenience and access in areas where laboratory facilities might not be easily accessible[29]. Point of care testing delivers reliable and timely HbA1c measurements that can allow for early detection of diabetes and allow healthcare providers to intervene early, optimize disease management and improve patient outcomes. Moreover, point of care testing is cost effective and simple so it is an attractive option for healthcare systems with limited resources[30].

CONCLUSION

The findings of this study add to the evidence for point of care HbA1c testing to be integrated into diabetes screening and monitoring programmes in resource constrained settings in a pragmatic manner to address the growing burden of diabetes in Pakistan. Further research arenas of study are suggested to validate the utility and feasibility of point-of-care HbA1c testing for diabetes mellitus screening and monitoring in resource constrained settings.

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