DIABETES;
DIAGNOSIS USING HbA1c AND ITS VARIATIONS AMONG TYPE-2 INDIVIDUALS ON REPETITION OVER A SHORT SPAN OF TIME- A RESEARCH STUDY

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ABSTRACT… Objectives: The objective of this study was to evaluate the variations in HbA1c on repetition over a span of about two weeks. Period: June 2015 to May 2016. Setting: Department of pathology, Continental Medical College Lahore, attached with Ch. Rehmat Ali Memorial Trust Teaching Hospital. Method: A total of 60 newly diagnosed or with no apparent diabetic complications were included in this study. Venous blood repeated samples were obtained for evaluation of HbA1c. Results: The result of our study show that in 65% of patients the repeated values were lower than the initial values, 25% were higher and 10% were below the diagnostic threshold. So it is indicated that HbA1c values vary over a span of time and repeated tests values should be considered for borderline patients. Conclusion: It is concluded from this study that values of HbA1c do differ on retest. Therefore, physicians should understand and not be confused with a little bit variations in values. It is recommended to repeat the test for newly diagnosed and borderline value patients to reach a final conclusion about diagnosis. It is also recommended that a separate study should be conducted to evaluate the cause/mechanism behind variations in HbA1c over a short period of time in our settings.

Key words: Type-2 diabetes, Diabetes mellitus, Glucose tolerance test, HbA1c level

INTRODUCTION
Diabetes Mellitus is one of the major and prevailing disease in the world. Its causes a great number of loss of lives and sufferings to the humans with different comorbidities such as obesity. According to one of the WHO estimates the number of affected individuals in the world will be increased to 366 million by 2030.¹

Diabetes is the cause of 3.97 million deaths in the world between the ages of 20-79 years which accounts for 6.8 percent deaths of all ages.

It is attributing more and more deaths each year. In Pakistan more than 88,000 deaths are the result of diabetes per year according to statistics.² Complications of Diabetes are the cause of doldrums which include amputation of foot, cardiovascular complications, retinopathies and nephropathies. About 1 percent blindness is caused by diabetes.

The objective of this study was to determine the HbA1c level of individuals with type-2 diabetes and compare its short term variation in the same individual.³

Different methods are used for the diagnosis of diabetes which include fasting blood glucose levels, oral glucose tolerance test and HbA1c levels, latter one is the most reliable and is considered as gold standard for diagnosis.

The criteria set by WHO for the diabetes diagnosis includes fasting Glucose level of 126 mg/dl or greater or after 2 hours of oral Glucose tolerance test it should be 200mg/ dl or more for a person to be labelled as diabetic. But these two criteria have variations from individual to individual.

The most recent Method adopted by WHO and American Diabetes Association is glycosylated
haemoglobin (HbA1c), which is considered gold standard so far. HbA1c levels 6.5 percent or more is considered diabetic with two consecutive days.\(^4\)

HbA1c levels in an individuals has advantages over other methods because there are only less than two percent variations among individuals and gives about last 3 months status. It is recommended to test HbA1c levels two to four times in a year.\(^5\)

HbA1c is more convenient and reliable test as compared other tests because it does not require fasting or other special preparation of the patient. It shows little variability over short span of time in individuals. One disadvantage of this test is that it is expensive.\(^6\)

In Pakistan HbA1c is also considered a reliable test to know the glycemic control of individual and also for the diagnosis of diabetes, but due to its high cost it is not more often offered, especially in the remote areas and small cities. Its need of the hour to implement it and provide facilities for proper diagnosis and management of diabetes.

**MATERIALS AND METHODS**

The present study was planned on blood samples of 60 individuals received for HbA1c evaluation from June 2015 to May 2016 in Pathology Labs of Continental Medical College Lahore. Ch. Rehmat Memorial Hospital serves as its teaching hospital which a 400 bedded hospital with different specialities. The samples were repeated after two week time and HbA1c values were recorded and compared to the previous values.

**Inclusion Criteria**

Volunteers were inducted in study with informed consent. Only individuals between the ages of 40 to 50 years were included in this study. All were having no apparent complication of diabetes or were newly diagnosed cases of diabetes.

**Exclusion Criteria**

Individuals with apparent complications of diabetes, drug associated hypoglycaemia and more than 50 years of age were not included in this study.

**Sampling and Examination of samples**

Fresh venous blood samples were obtained from patients and processed in the lab for HbA1c evaluation. The samples were repeated after two weeks and proper record of the patients was maintained. The values of Hb1Ac were recorded on the basis of chromatography. The two values were then compared for any change.

**Statistical analysis**

The statistical analysis was done according to WHO criteria for the diabetics. All values were carefully recoded. The variation on repeating the tests were recorded and presented as histogram.

**RESULTS**

In our study out of 60 patients on which this study was conducted and the results of 2nd values of HbA1c were compared with the first values that were recorded about two weeks earlier.

The results of our study show that in 65% of the individuals tested the repeated values were lower than the first values. Among these individuals 20 percent show a fall of 0.3% than the mean fall in the values, with 30 percent of individuals a fall of more than 0.5%. About 10% of individuals even show less than 6.5% of diagnostic threshold. In 25% of individuals the test values repeated in around 2 weeks were higher than the first test values. These are shown in table below:

<table>
<thead>
<tr>
<th>Total No. of Individuals</th>
<th>Individuals with lower repeated values</th>
<th>%age of individuals with lower values</th>
<th>Individuals with higher repeated values</th>
<th>%age of Individuals with higher repeated values</th>
<th>Individuals with repeated values lower than the threshold values</th>
<th>%age of Individuals with repeated values lower than the threshold values</th>
</tr>
</thead>
<tbody>
<tr>
<td>60</td>
<td>39</td>
<td>65%</td>
<td>15</td>
<td>25%</td>
<td>6</td>
<td>10%</td>
</tr>
</tbody>
</table>

Table. Showing the results of study
DISCUSSION
HbA1c is gold standard for the diagnosis of Diabetes mellitus. Although it is expensive for developing countries like Pakistan but it is quite useful. It is one of the most important criteria for the diagnosis of diabetes. The repeat values of HbA1c in this study show that theses vary over a short span of time and should be repeated to reach a final conclusion in a newly diagnosed patient.

Different factors alter the status of HbA1c levels, which includes different haemopathies, immune disorders, iron deficiency anemia, vitamin deficiency, antimicrobials, antivirals and even ethnicity. Therefore, HbA1c level of 6.3% as lower limits can be considered as diabetic. The factors that increase the life span of RBC’s increase its levels while factors that decrease red blood cells life span decrease HbA1c levels. In our study we didn’t found the exact cause/mechanism involved in the variation of values over a short span of time.7

The variations of values below and above the diagnostic value are close to a study conducted by Mc Donald and Warren in 2014. No significant factors was found that was responsible for the variation in values.8

This study shows that it is quite common the repeat values for HbA1c do differ over a short span of time.

CONCLUSION
It is concluded from this study that values of HbA1c do differ on retest. Therefore, physicians should understand and not be confused with a little bit variations in values. It is recommended to repeat the test for newly diagnosed and borderline value patients to reach a final conclusion about diagnosis. It is also recommended that a separate study should be conducted to evaluate the cause/mechanism behind variations in HbA1c over a short period of time in our settings.

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REFERENCES