Reference Range of Fasting Blood Glucose in Sudan

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Abstract

Background: Due to lack of locally derived reference values; clinicians use reference intervals derived from western population. But, studies conducted on different reference values have indicated differences between locally and western derived reference values. The normal values of Fasting Blood Glucose (FBG) in Sudanese must be established for the clinical diagnosis of DM.

Objectives: The objective of this study is to establish the normal values of FBG in Sudanese healthy adults and compare the results with the international values.

Methods: Cross sectional study was conducted during 2016 - 2018 in Sudan covered Khartoum state, Northern state, Gezira state, Red Nile state and North Darfur state, on adults of ages between 20 - 60 years and not known to be diabetic or suffering from any chronic illness. 1096 participants were assessed by a questionnaire covering age, family history of Diabetes Mellitus, physical activity, daily caloric intake and smoking. BMI was calculated by measuring weight and height by weight and height standard scales. A sample of venous blood was taken for FBG measurement using autoanalyzer A15 machine. Correlations between the variables were estimated and P value ≤ 0.05 was considered statistically significant.

Results: The mean of age, BMI and Hb A1c was found to be 25.1 ± 9.5 years, 22.8 ± 4.8 and 4.6 ± 0.9% respectively. The mean of FBG was 74.3 ± 13.8 mg/dl with a range of 60.5 to 88.1 mg/dl. FBG was found to be positively correlated with Hb, RBCs and platelets counts with significant p value (P value ≤ 0.05). There was no significant correlation observed between FBG and HbA1c level (r = -.003, P value = .957).

Conclusion: This study showed significant variations in the level of FBG of healthy Sudanese in comparison with the reference ranges of international parameters, so the normal values for FBG in Sudanese is lower than that currently use.

Keywords: FBG; Reference Ranges; Normal Values

Introduction

From 1987 to 1991, the International Federation of Clinical Chemistry (IFCC) published a series of 6 papers, in which it has recommended that each laboratory should follow defined procedures to produce its own reference values [4-9]. Although there were very important developments and implementations between the 1990s and 2008 [10-13]: the C28-A3 guideline, published in 2008 by the Clinical and Laboratory Standards Institute (CLSI) and IFCC constituted the most significant step in the development of RIs and is still in
Reference Range of Fasting Blood Glucose in Sudan

According to a report published by the international diabetes federation (IDF) Middle East and North Africa (MENA), there was over 1.4 million cases of diabetes in Sudan in 2015 [15].

Differences in the normal values in Sudan have been documented in some hematological values [16-20], respiratory function tests parameters [21], Renal functions test [22], serum electrolytes [23] and mean of glycated hemoglobin (Hb A1c) [24-28].

According to the American Diabetes Association, a normal fasting blood glucose level is less than 100 mg/dl, if fasting glucose is between 100 and 125 mg/dl it may be considered a prediabetic state. The diagnosis of DM is confirmed if there are two consecutive elevated fasting blood glucose tests, greater than 125 mg/dl [29].

Currently, there are no known big scale studies conducted to investigate the normal reference range of FBG in Sudanese people, and the normal reference range of FBG in Sudanese hospitals and clinics is obtained from non-Sudanese subjects depending on the international American and British Guidelines. In this study, the normal level in healthy Sudanese people from all over Sudan was investigated.

Methods

A Cross sectional study was conducted during 2016 - 2018 on Healthy Sudanese subjects of both sexes with age group 20 - 60 years. 1096 Sudanese adult volunteers were included and the study covered Khartoum state, Northern state, Gezira state, Red Nile state and North Darfur state. The exclusion criteria of this study included: Pregnant ladies, Diabetes mellitus, Hypertension, Renal failure, Liver disease, Cancer, Chronic diseases (cardiac diseases, TB, asthma, thyroid disorders), Hematological disorders. Recent acute diseases (Malaria, typhoid fever...etc), Lactation. History of recent surgery (splenectomy), History of schistosomiasis and Subjects not consenting. Written consents were obtained from all participants after fully explaining to them the project. A questionnaire was filled by all volunteers to obtain the data about name, age, address, medical history, drug use, and lifestyle. Weight, height, and blood pressure were measured with standard techniques. Complete clinical examination was performed. After informed consent, 5 ml of venous blood was collected by a standard procedure from each participant under complete aseptic conditions in the morning and after an overnight fasting. 2.5 ml was placed in fluoride oxalate containers, and then used for FBG measurement with auto analyzer A 15. The other 2.5 ml was placed in EDETA containers for measurement of CBC and HbA1c. All techniques and equipment's were standardized. Data was analyzed using the SPSS computer program version, (t-test was used for comparison of means and p. value ≤ 0.05 was taken as significant).

Ethical consideration

Ethical Approval of this study was obtained from the Federal Ministry of Health in Sudan (FMOH) and The National Ribat University (NRU). The objectives of the study were explained to all individuals participating in the study. An informed consent was obtained from each participant in the study.

Results

A total of 1096 volunteers were identified as eligible; satisfying the inclusion criteria and approved to be enrolled after filling the consent, filling the questionnaire and fit on the physical examination.

444 of the participants were living in Khartoum state, 174 in Red Sea state, 91 in Gezira state, 215 Northern state and 172 were from North Darfur state.

808 (73.3%) of the study sample were females and 272 were males (24.8%) and 16 were missing (1.5%).
The mean of age was found to be $25.18 \pm 9.58$ years with a range of 20 - 60 years.

The mean of BMI was found to be $22.8 \pm 4.8$ and Hb A1c was $4.6 \pm 0.9\%$ (Table 1).

The mean of FBG was $74.3 \pm 13.8 \text{ mg/dl}$.

FBG was found to be higher in Sudanese females in compared to Sudanese males with significant p value (.001) (Table 2).
The highest value of FBG was obtained in the Western state and the lowest value was obtained in the Northern state (Table 3).

<table>
<thead>
<tr>
<th>State</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Khartoum State</td>
<td>74.3</td>
<td>13.8</td>
</tr>
<tr>
<td>Western State</td>
<td>76.7</td>
<td>11.4</td>
</tr>
<tr>
<td>Gezira State</td>
<td>73.1</td>
<td>14.9</td>
</tr>
<tr>
<td>Northern State</td>
<td>72.0</td>
<td>13.3</td>
</tr>
<tr>
<td>Red Sea State</td>
<td>75.8</td>
<td>15.7</td>
</tr>
<tr>
<td>Total</td>
<td>74.3</td>
<td>13.8</td>
</tr>
</tbody>
</table>

*Table 3: Mean of FBG according to Sudanese Sates.*

FBG was found to be positively correlated with Hb, RBCs and platelets with significant p value (P value ≤ 0.05). There was no significant correlation observed between FBG and HbA1c level (r = -.003, P value = .957).

<table>
<thead>
<tr>
<th>FBG</th>
<th>Hb A1c</th>
<th>HGB g/dl</th>
<th>RBCs*</th>
<th>WBCs*</th>
<th>PLT*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Correlation</td>
<td>-.003</td>
<td>-.249**</td>
<td>-.263**</td>
<td>-.029</td>
<td>.182**</td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td>.957</td>
<td>.000</td>
<td>.000</td>
<td>.565</td>
<td>.000</td>
</tr>
</tbody>
</table>

**. Correlation is significant at the 0.01 level (2-tailed).**

*Correlation is significant at the 0.05 level (2-tailed).*

*Table 4: FBG correlation with FBG, Hb, RBCs, WBCs and Platelets.*

**Discussion**

As FBG c is now used largely for DM diagnosis, the normal values of FBG in Sudanese have been addressed by this study.

Since FBG reference intervals currently used in Sudan have been adopted from textbooks or guidelines referring mainly to European or American populations and according to some discrepancies in the normal reference intervals observed between Sudanese populations compared to European and American countries which has been documented in hematological values [16-20], respiratory function tests parameters [21] Renal functions test [22], serum electrolytes [23] and mean of glycated hemoglobin (Hb A1c) [24-28]; this study was conducted to investigate the normal FBG level in adult Sudanese.

The population selected for this study was 1096 subjects. According to the international recommendations of the IFCC-LM and the CLSI, this size of sample can be considered to be representative of the adult population of the studied provinces (number of individuals ≥ 120 for each group) [36].

The Normal values of FBG in this study were found to be 74.3 ± 13.8 mg/dl (a Range of 60.5 - 88.1 mg/dl). This finding is different from the international range (100 - 125 mg/dl) [29] but it agreed with Albadari and Musa [30] study in Nile River state where the range of normal FBG in Sudanese was found to be 66.5 - 95.7 mg/dl. This study indicates that the diagnosis of DM by FBG in Sudanese subjects needs to be revised.

There was no significant correlation observed between FBG and HbA1c level (r = -.003, P value = .957). This finding is not in agreement with Van’t Riet, et al. study who found moderate correlation between FBG and HbA1c level [31].

Reference Range of Fasting Blood Glucose in Sudan

According to our study, Sudanese population has clearly lower normal values of FBG when compared to international reference values. Subsequently, using these international thresholds in our local population might result in under diagnosing diabetes and slowing the recognition of cases of poor control subjecting them to complications of the disease before aggressive measurement can be instituted.

Conclusion

In conclusion this study showed significant variations in the level of FBG of healthy Sudanese in comparison with the reference ranges of international parameters.

Acknowledgement

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