Original Research Article

Reference range establishment for blood glucose and lipid profile in healthy adults

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Abstract

Context: Reference ranges in clinical laboratories are commonly based on results of measurements in reference to western population or are taken from the western literature. The serum lipid levels even in healthy normal population are affected by a number of factors such as age, sex, racial differences, dietary factors, socio- economic status, geographic conditions which influence these values. The reference values are thought to aid the clinician in medical decision making process. Hence there is need for establishment of reference range for all biochemical parameters which is population specific. **Aims:** To measure blood glucose and lipid profile and to develop reference range for blood glucose and lipid profile in Gulbarga population **Methods:** The study comprised of 1062 normal healthy subjects in the age group of 20 to 60 years. The healthy individuals visiting the medical OPD were considered for the study. Their fasting samples were analyzed for fasting blood glucose and lipid profile. Post prandial samples were analyzed for blood glucose. All the parameters were analyzed using semiautomatic analyzer Erba Chem-7. The mean values obtained were statistically analyzed. **Results:** The reference range obtained for blood glucose from this study was 67-103 mg/dL, 78-133 mg/dL for fasting and post prandial respectively. The reference range for lipid profile was 34-51 mg/dL, 70-159 mg/dL, 63-162 mg/dL, 138-226 mg/dL for HDLc, LDLc triglycerides, and total cholesterol respectively. The values obtained for total cholesterol, triglycerides and LDLc was comparatively high and values for HDLc was less compared to textbook values. The reference range for blood sugar remained almost same. **Conclusions:** The results obtained showed variation from the values currently used in the laboratory. There for it is inferred that reference range obtained for selected population could be different. Hence there is a need for development of reference range for all biochemical parameters in a selected population in more partitioned groups with larger sample size which could be of more significance to the physician.

Key Words: HDL, LDL, Reference range, Reference limit.

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Email: skumarglb@gmail.com
Received Date: 10/01/2018 Revised Date: 14/02/2018 Accepted Date: 01/03/2018
DOI: https://doi.org/10.26611/1002531

Access this article online	
Quick Response Code:	Website: www.medpulse.in
	Accessed Date: 03 March 2018

INTRODUCTION

Medicine is an art and a science in the service of fellow human beings. To improve the health of the patients, physicians collect empirical data, interpret these data using scientific knowledge and professional experience, make decisions concerning diagnoses, recommend preventive measures, and execute therapeutic actions. There is a fundamental limitation in this activity; absolute health does not exist. Health is necessarily a relative concept.[1] The WHO defined Health as "a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity".[2] Health of an individual is conceptually different in different countries, in the same country at different times and in same individuals at different ages. It is thus a relative and not an absolute state. A patient's laboratory result simply is not medically useful if appropriate data for comparison are lacking. The only index for evaluating the health status is with the aid of reliable validated laboratory data practiced in any section of laboratory medicine.[3] Thus the

How to cite this article: Bhuvanendranath H, Ronad S S, Shravan Kumar. Reference range establishment for blood glucose and lipid profile in healthy adults. *MedPulse International Journal of Biochemistry.* March 2018; 5(3): 77-80.
https://www.medpulse.in/Biochemistry/

central role of the laboratory scientist is to aid the clinician in interpreting observed values by providing relevant reference values and presenting them in a convenient form which helps clinician in decision making process. The interpretation of laboratory data underpins most important clinical decisions. Therefore, reliable reference values are required for all tests in the clinical lab and must be provided by clinical labs and diagnostic test manufacturers. The reference intervals (often known as normal values or expected values) are poorly defined and certainly not determined by a uniform process.[3-5] Therefore there is a absolute need for reference values in clinical chemistry lab for all biochemical parameters. Almost all laboratories in India use the reference values published either from available textbooks or from diagnostic kit inserts without giving details of the original source of the data. In view of our country's enormous ethnic and racial diversity, it is necessary to define reference range specific for Indian population. There is an obvious need for health associated reference value for quantities measured in the clinical chemistry laboratory. Diabetes mellitus and coronary artery disease are major cause of morbidity and mortality in our country. The concept of reference values for routine monitoring of blood glucose in diabetes mellitus and lipid profile in patients at risk of coronary artery disease are of great significance in a selected population. Hence, there is need for development of reference range for blood glucose and lipid profile in the defined population.

MATERIAL AND METHODS

The present study comprised of 1062 normal healthy subjects in the age group of 20 to 60 years. Individuals visiting the medical OPD and general hospital attached to medical college, Gulbarga were considered for the study. The subjects included in the present study were selected after taking a detailed medical history and physical examination and only those individuals who fulfilled the inclusion and exclusion criteria were considered for the study. The study was conducted following a well defined protocol.

Table 1: Criteria's formulated for selection of subjects

Inclusion criteria	Exclusion criteria
Normal healthy subjects aged between 20 – 60 years, Both sexes from urban and rural area included	Patients with history of diabetes mellitus dyslipidemias, endocrine disorders, obesity, coronary artery disease, pregnancy, hypertension, malabsorption syndromes, metabolic abnormalities, hepatic or renal disease, history of smoking or liquor consumption or taking oral contraceptives

Sample collection: Under aseptic conditions 2ml of venous fasting blood sample was collected from anticubital vein in plain vacuum tube containing clot activator for lipid profile and 1ml in fluoride vacutainer for fasting blood glucose estimation. Again 1ml blood was collected in fluoride vacutainer for post prandial blood glucose estimation two hours after consumption of food. All the pre-analytical factors were standardized and the study parameters were analyzed using separated serum.

Method of analysis: All serum samples were analyzed by using ERBA Chem 7 Semiautoanalyzer. The precision of the instrument was checked on regular occasions. All the analytical procedures were standardized; the reagents were calibrated to the instrument before sample analysis was done. The glucose was measured by glucose – oxidase peroxidase method [6, 7], while the total cholesterol, triglycerides, HDL and LDL were measured by cholesterol oxidase PAP method[8], glycerol phosphate oxidase trinder method[9,10], immunoinhibition method[11] and Friedewald formula[12] respectively.

Statistical Analysis: All the data obtained was expressed as mean±2SD. Data analysis was done by using Statistical Software (SPSS-17). Kolmogorov-Smirnov (Z-test) was applied for all the parameters. The reference limits are defined as the central 95% of the population comprised between quantiles 2.5 and 97.5, leaving aside 2.5% of the individuals on both sides of the distribution[13] and reference limits were estimated following standard methods of the International Federation of Clinical Chemistry (IFCC).[14]

RESULTS

In the present study reference ranges for blood glucose and lipid profile were calculated following standard methods of the International Federation of Clinical Chemistry (IFCC). The reference range obtained for fasting blood glucose was 67-103 mg/dL, which is slightly wider than that used currently in the laboratory. The mean value for FBS was 84.89mg/dL, the minimum value being 67mg/dL and maximum value being 110 mg/dL. Gaussian distribution of values was obtained which were not statistically significant ($p > 0.05$). The reference range obtained for PPBS was 78-133 mg/dL, which is almost literature referred values. The mean value obtained was 103.19. The minimum value was 72 and maximum value was 140. There was no significance in Gaussian distribution of values ($p > 0.05$). The reference range obtained in this study for total cholesterol was 138-226 mg/dL which is slightly widened. The mean value was 170.86. The minimum value was 121 and maximum value 238. A Gaussian distribution of values was obtained and the p value was >0.05. The reference range obtained

in this study for triglycerides was 63 – 165 mg/dL. The mean value was 106.11. The minimum value was 54 and maximum value 187. A Gaussian distribution of values was obtained which was not significant (p>0.05). The reference range obtained in this study for HDLc was 34 – 51 mg/dL, which is comparatively less than the reference range used currently in the laboratory. The mean value was 41.17. The minimum value was 27 and maximum value was 58. Similarly the reference range obtained in this study for LDLc was 70 - 159 mg/dL, which is widened compared to the reference range currently used in the laboratory. The mean value was 108.50. The minimum value was 64 and maximum value was 186. There was no significance in Gaussian distribution of values obtained for both HDLc and LDLc (p>0.05).

Table 2: Reference range obtained for blood glucose and lipid profile

Parameter	Reference range	Reference range obtained from this study
Fasting blood glucose	65-110 mg/dL	67-103 mg/dL
Post prandial blood glucose	120-140 mg/dL	78-133 mg/dL
Total cholesterol	150-250 mg/dL	138-226 mg/dL
Triglycerides	40-160 mg/dL	63-162 mg/dL
HDLc	30-65 mg/dL	34-51 mg/dL
LDLc	<100 mg/dL	70-159 mg/dL

To summarize, when the reference range obtained was compared with that currently used in our laboratory, it was found that there was a shift in the reference range for the analytes- total cholesterol, TG, HDLc, LDLc. The reference range for TC, LDLc had widened and reference range of HDLc was comparatively less than the reference range used currently in the laboratory.

DISCUSSION

The concept of reference intervals was introduced by international federation of clinical chemistry (IFCC) to avoid the problems with normal values and values obtained from an individual under clinical investigation. Reference limits are descriptive of a homogenous population as close as possible to the patient and specific to the measurement procedure used. Reference values, developed by individual laboratories for the population in which they are located, are very essential since they play a very important role in diagnosis and therapeutic clinical decisions, positioning the patient in regard of the adopted reference system, assessing significant biological variations, evaluating the probability of occurring illness and assessing different clinical settings.[15] Using reference limits, one can continue with theoretical situations when the biological variations are not homogenous, and further elaborate on the different situations in monitoring, which have different concepts and models like repeated testing, spontaneous and expected course, toxicity of therapeutic agents, follow-up and progression of disease, and managing therapy. In India most laboratories follow reference intervals established in the western population. The reference intervals can be questioned because of differences arising due to variations in diet, lifestyle etc in western population compared to Indian population. There are few studies which have mentioned the establishment of reference range in some ethnic populations. The diverse findings in these studies though attributed to socioeconomic status, nature of diet/ dietary fat and genetic predisposition could be different[35]. In light of these findings, we therefore felt essential to establish reference range of some parameters like plasma glucose, serum lipids and lipoproteins in population of Gulbarga region. Cardiovascular diseases are the major cause of death in our society. The ability to prevent the development of atherosclerosis or, alternatively, to decrease established atherosclerotic plaques, often referred to as regression, has major implications for public health. Whereas the incidences of coronary artery disease (CAD) were halved in the West in the past 30 years, the rates doubled in India with no signs of downturn. It appears that the CAD epidemic could explode in parallel with affluence and urbanisation in rural villages unless the gravity and magnitude of the problem is recognised and immediate action is taken. Thus a reassessment of plasma lipids in a modern population becomes a necessity to recognize the defects in our health strategies.[16] In this present study, an attempt has been made to know the influence of demographic factors on the values of analytes like plasma glucose, lipids and lipoproteins. Information about the volunteers from whom the healthy population was derived was obtained from their questionnaire response and general physical examination without further verification. The study which aimed at establishing reference range for biochemical parameters like plasma glucose, lipids and lipoproteins in population of Gulbarga region showed varying results when compared to the values that are currently being used in our hospital which are taken from western literature. The results of the study showed varying values for blood glucose and lipid profile when compared to the values which are followed in our laboratories provided by the diagnostic kit inserts of the western literature. The reference ranges obtained from the study has shown a shift in parameters like total cholesterol, triglycerides, HDL and LDL. The reference range for blood glucose was found to be unchanged. The possible causes for shift in the parameters could be because of lifestyle changes in population of Gulbarga

region and changing dietary habits because of urbanization which explains the relative elevation in the reference range of lipids and lipoproteins. From present study it appears that establishment of reference range for TC, TG, HDL and LDL would help larger percentage of population being misclassified as normolipemics or hyperlipemics. The findings of the study clearly indicate need for development of reference range for all biochemical parameters and also regular review of reference values.

CONCLUSION

The values obtained from the study showed deviation from the values provided by the diagnostic kit inserts or literature. The results obtained from this study for biochemical parameters of lipid profile are significant after detailed analysis for the defined population. As a uniform dietary pattern was not followed in this study, values might show variations. Hence, from this study it can be concluded that the reference range obtained for biochemical parameters of lipid profile observed in defined population could be significantly different from the values provided by the diagnostic kits. Establishing reference range for biochemical parameters in a selected population in more partitioned groups with larger sample size will be of great significance to the clinicians in making the decisions.

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Source of Support: None Declared
Conflict of Interest: None Declared