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Reference interval for lipid profile in North Indian population from Rajasthan according to various partitioning criteria

Dharamveer Yadav [a,*], Monika Gupta [b], Sandhya Mishra [a], Praveen Sharma [c]

[a] Department of Biochemistry, SMS Medical College, Jaipur, India
[b] Mahatma Gandhi Medical College, Jaipur, India
[c] All India Institute of Medical Sciences, Jodhpur, India

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ABSTRACT

Objective: Lipid profile parameters are influenced by various factors like age, ethnicity, diet, genetic and gender differences hence it is essential to establish reference range of the values of serum lipids for a given population in India. We have planned this study to evaluate the reference values of lipid profile of a North Indian population according to the guidelines of the National Cholesterol Education Program (NCEP) of the USA.
Design and methods: The present study was conducted on 2021 apparently healthy individuals of North Indian origin ranging in age from 15 to 60 years, who were selected randomly using defined criteria. Fasting samples were analyzed for total cholesterol, triglyceride, HDL-C and LDL-C. Data were analyzed for middle 95th percentile (2.5th–97.5th percentile), median and 95% confidence interval using SPSS software package version 10.0.
Results: No substantial difference could be observed between male and female and vegetarian and non-vegetarian, in cholesterol, triglyceride and LDL-C levels. However HDL-C reported higher limit in female as compared to male (33–64 vs 32–58 mg/dl). Similarly upper limit of HDL-C in vegetarians were higher than non-vegetarian (value 32.8–64.92 vs 30.72–58.10 mg/dl). Median value for cholesterol, triglyceride, LDL-C progressively increased in different age groups (<20, 20–40 and 41–60 years). No marked difference was observed in reference interval of these parameters in rural and urban populations.
Conclusion: It can be suggested that lipid values obtained in this study can be used as the reference value, based on which clinical correlation can be made.

1. Introduction

The health of an individual is conceptually different in different countries, in the same country at different times and in the same individuals at different ages. It is thus a relative and not an absolute state. This means that the condition of individuals must be related to or compared with reference data. On comparing the individuals' data collected during the medical interview, clinical examination, and supplementary investigations with the reference data, the condition of the individuals can be interpreted. A patient's laboratory results simply are not medically useful if appropriate data for comparison are lacking. Currently, developing countries like India are facing serious public health challenges like obesity, cardiovascular disease, diabetes and infectious diseases. In this arena, the clinical laboratory plays a major role in the early diagnosis of life threatening disease and also provides valuable information about the health of an individual. It is thus the central role of the laboratory scientist to aid the clinician in interpreting observed values by providing relevant reference values and presenting them in a convenient and practical form. The concept of reference interval was introduced by the International Federation of Clinical Chemistry to avoid problems with normal values and values obtained from an individual under clinical investigation [1]. According to the IFCC, it is necessary for every laboratory to have its own set of reference limits.

Reference values used in India are usually based on results of measurements in advanced countries, taken from the literature (of advanced countries) or from package inserts that accompany reagent kits. There is a great variation of plasma lipid levels in different populations which usually are affected by age, ethnicity gender, food habits, life style and socio-economic status [2]. Different methodologies adopted for the determination of lipids also may have some role in variation which could not be ignored. In Clinical Chemistry, the use of the term lipids generally refers to lipoprotein metabolism and atherosclerosis, a cause of coronary heart disease (CHD) [3]. Available global data have clearly established the relationship of lipids and other risk factors with cardiovascular and cerebrovascular events [4,5]. However, in India most of the laboratories follow the reference intervals established in the Western population; these usually do not match with the Indian population especially in the case of lipid profile. It is obvious from this study that there is a need to establish a reference range of the values of serum lipids that are applicable to specific populations rather than take a set of reference values determined

* Corresponding author. Tel.: +91 9413841965.
E-mail address: dharam143s@gmail.com (D. Yadav).

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Table 1
Values of quality control Levels I and II from Bio-Rad, mean obtained and day to day percent of coefficient of variation (CV).

Analyte	Reference mean		Mean obtained		% of CV	
	Level I	Level II	Level I	Level II	Level I	Level II
Cholesterol	250.0	95.2	251.6	95.6	2.4	1.3
Triglycerides	184.0	90.7	183.2	89.5	2.3	1.8
HDL-C	65.0	23.4	65.3	23.1	2.7	2.1

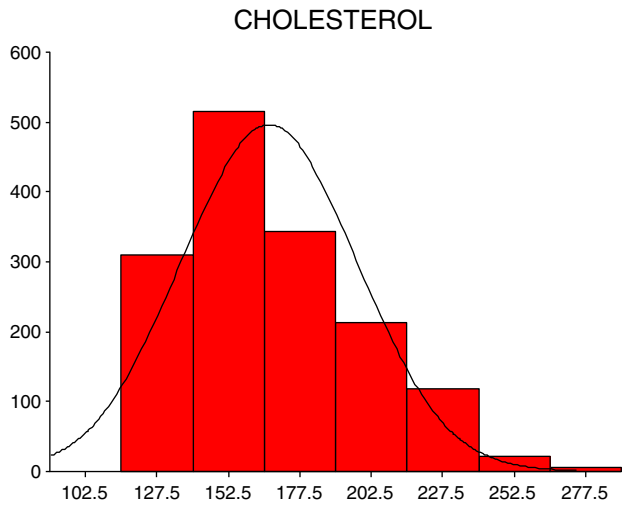

Fig. 1. Distribution curves of lipid profile parameters (cholesterol).

for one population and apply it to another population as only a few studies have been carried out in other regions of India [6–11].

The present study was, therefore, designed to establish the reference interval of lipid profile in a reference population which was taken from Jaipur (Rajasthan) and adjoining areas representing North Indian population. The current study is thus conducted so that parameters evaluated in the healthy defined group of individuals would serve as the reference values for the reference population.

2. Materials and methods

The study was conducted in the Department of Biochemistry at S.M.S. Medical College and Associated Group Hospitals, Jaipur to examine reference interval of triglycerides, cholesterol, HDL-C and non-HDL-C. The reference population of either sex ranging in age from 15 to 60 years, from diverse socio-economic backgrounds with variable dietary habits was selected randomly using defined criteria from Jaipur and adjoining areas. In all 2021 apparently healthy individuals of north Indian origin were initially enrolled. All the individuals were called personally to the laboratory and screened with a history and physical examination and routine laboratory investigations to rule out any obvious intercurrent disease. Females were examined for pregnancy by a urine dipstick examination. Information regarding age, sex, disease if any, dietary habits, physical activity, smoking or alcoholic habit, anthropometric parameters were obtained with respect to each subject and carefully recorded. The institutional ethics committee approved the study and informed consent was obtained from the study population. This was a minimal risk study and was conducted in accordance with the protocol and Good Clinical Practices to ensure protection of all aspects of the ethical rights and welfare of research participants. Out of 2021 participants 494 were excluded using appropriate exclusion criteria defined by IFCC and NCCLS [12]. Finally 1527 individuals were included in the study. Irrespective of seasonal variations samples were collected over a period of twelve months from April 2011 to March 2012.

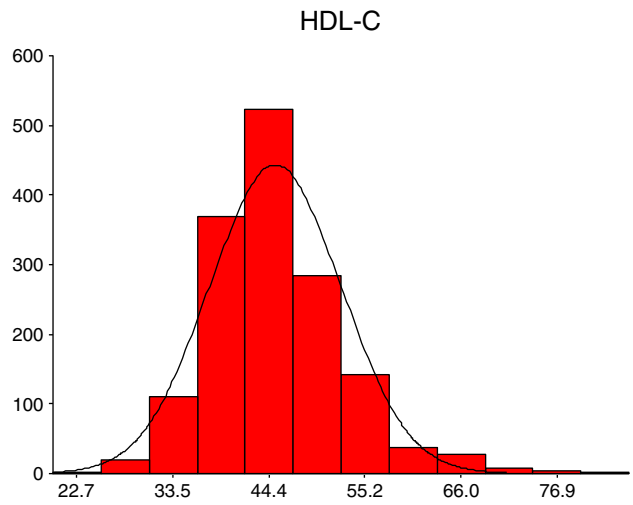

Fig. 3. Distribution curves of lipid profile parameters (HDL-C).

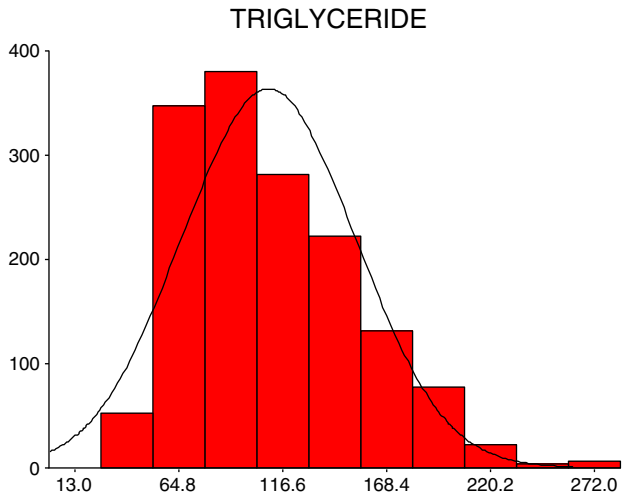

Fig. 2. Distribution curves of lipid profile parameters (triglyceride).

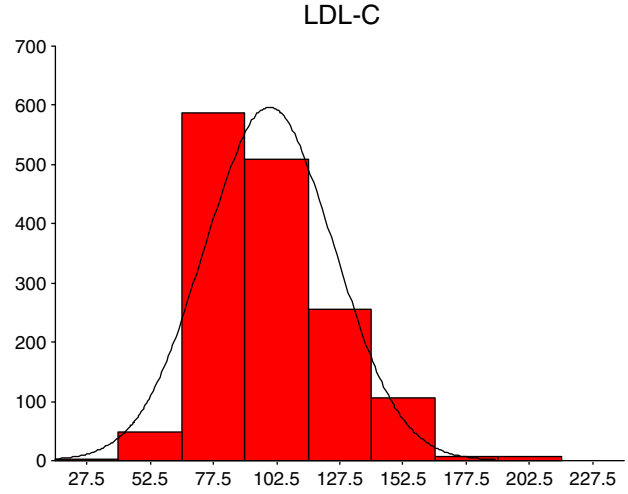

Fig. 4. Distribution curves of lipid profile parameters (LDL-C).