



EVALUATION OF REFERENCE INTERVAL OF SERUM LIPID PROFILE IN RURAL AREA OF KONKAN REGION FROM MAHARASHTRA STATE

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ABSTRACT

The aim of the study was to evaluate the reference interval of serum lipid profile from rural area of Konkan region of Maharashtra state. Study Design is a retrospective study. Serum lipid profile parameters were estimated by standard methods on Transasia Erba -200 Fully Automated Chemistry Analyser using Erba Diagnostic kits manufactured by Transasia Biomedical Pvt. Ltd. The present study includes total 554 healthy controls (330 males and 224 females) in the age group of 20 to 45 years. The serum total cholesterol levels in males were 160.09 ± 25.25 mgs/dl and in females were 153.51 ± 33.16 mgs/dl. The serum triglyceride levels in males were 129.07 ± 45.87 mgs/dl and in females were 129.88 ± 51.43 mgs/dl and HDL – Cholesterol levels in males were 40.35 ± 13.04 mgs/dl and in females were 47.84 ± 14.30 mgs/dl. The statistical analysis was done by student's t-test. The serum total cholesterol is lower in females as compared to males but it was found non-significant. The significant difference was observed in HDL – cholesterol levels in males and females from the same region. Conclusion: In the present study serum total cholesterol, triglycerides, LDL and VLDL – Cholesterol were non-significant in male as compared to females. It was found that HDL- cholesterol levels were significantly higher in females as compared to males. This may be because of estrogen levels in female, which increases HDL- Cholesterol levels. The present study further suggests that the lipid profile values obtained in this study can be used as the reference values for rural area of Konkan region of Maharashtra state.

KEY WORDS: Lipid profile, Reference interval, Konkan region.



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INTRODUCTION

Reference interval means the normal range of specific parameter obtained from a reference population of particular region. The reference interval of particular parameter in any laboratory depends on the reagents, specific methodology and the instruments used. It also varies with age, gender, region, dietary patterns and physical activities. The reference interval is used to compare and evaluate patient's reports of particular region. The diagnosis, monitoring the disease process and prognosis of disease is dependent on the patient's reports. Lipid profile includes total cholesterol(TC), triglycerides(TG), HDL-Cholesterol(HDL-C), LDL-Cholesterol(LDL-C), VLDL-Cholesterol(VLDL-C). As per the International Federation of Clinical Chemistry (IFCC) it is necessary for every laboratory to establish their own reference intervals. However in India most of the laboratories follow reference intervals established in the western population¹⁻³. In Indian laboratory setup the reference intervals have been derived from Western literature, text books or population based study from different countries. It varies from country to country and also region to region within the same country. Therefore it is necessary to establish our own laboratory reference intervals or regional reference intervals so that it will be helpful to clinicians to correlate it with clinical history of the patients. So far very few studies on Indian reference interval of various parameters from rural population of Konkan region of Maharashtra state are available. Therefore the present study is carried out to evaluate the reference intervals of serum lipid profile parameters from rural population of Konkan region of Maharashtra state and compare these data with previously published literature.

MATERIALS AND METHODS

The present study was conducted in the Department of Biochemistry, B. K. L. Walawalkar Rural Medical College & Hospital, Sawarde, Dist –Ratnagiri, Maharashtra state, India. It is a retrospective observational study. The normal healthy individuals from rural area of Konkan region of Maharashtra state who had undergone routine health checkup at our hospital are included in the present study. On the basis of clinical examination and biochemical investigations all these subjects were considered as healthy. The present study includes normal 554 healthy controls (330 males and 224 females) attending OPD having age group 20 to 45 years from both genders. The patients suffering from diabetes mellitus, hypertension, cardiovascular diseases, Liver diseases, Kidney diseases, Tuberculosis and pregnant women were excluded from the present study. Only normal healthy controls were included in the present study. The fasting blood samples were collected in plain bulbs without any anticoagulant. After clotting at room temperature, the clot was separated from the serum by centrifugation at 3000 rpm for 10 minutes. The clear supernatant (Serum) was immediately transferred in another dry tube. Serum TC, TG and HDL –C were measured by standard method⁴⁻⁶ on Transasia Erba -200 Fully Automated Chemistry Analyser using Erba Diagnostic kits manufactured by Transasia Biomedical Ltd and LDL-C, VLDL-C were calculated by using Friedwald's Equations. The statistical analysis was done with the Excel 2007 software for the determination of the mean \pm SD and the results were compared between males and females using the Student's *t*-test.

RESULTS AND DISCUSSION

Table 1
Lipid profile parameters of healthy controls from rural population of Konkan region of Maharashtra state

Lipid Profile Parameters	Males (N=330) Mean \pm S.D.	Females (N=224) Mean \pm S.D.	Statistical Significance
Serum Total Cholesterol(mg/dl)	160.09 \pm 25.25	153.51 \pm 33.16	Non-Significant P > 0.05
Serum Triglycerides(mg/dl)	129.07 \pm 45.88	129.88 \pm 51.43	Non-Significant P > 0.05
Serum HDL – Cholesterol (mg/dl)	40.35 \pm 13.04	47.85 \pm 14.30*	Significant P < 0.05
Serum LDL – Cholesterol (mg/dl)	84.56 \pm 32.32	87.90 \pm 27.32	Non-Significant P > 0.05
Serum VLDL – Cholesterol (mg/dl)	28.31 \pm 16.48	30.53 \pm 24.68	Non-Significant P > 0.05
LDL-C: HDL-C Ratio	2.33 \pm 0.93	2.17 \pm 0.97	Non-Significant P > 0.05

Table 2
Distribution of lipid profile values of healthy controls as per National Cholesterol Education Program (NCEP) and Adult Treatment Panel III classification from rural population of Konkan region of Maharashtra state

Parameters	Desirable levels or normal levels	Borderline high levels
Serum Total Cholesterol	< 200 mg/dl Males: 82.73 % (273/330) Females: 87.5 % (196/224)	200-239 mg/dl Males: 17.27%(57/330) Females:12.5%(28/224)
Serum Triglycerides	< 150 mg/dl Males:78.78% (260/330) Females: 78.13%(175/224)	150-199 mg/dl Males:21.22% (70/330) Females: 21.87%(49/224)
Serum LDL - Cholesterol	< 100 mg/dl Males:76.36% (252/330) Females: 82.59%(182/224)	100-129 mg/dl Males:23.64%(78/330) Females: 17.41%(42/224)

Table 3
Comparison of lipid profile parameters in Present study with previous workers

Lipid profile parameters	Results of present study		Pushpa Durgawale et al Mean \pm SD	Yuthika Agrawal et al Mean \pm SD	Venkataraman D. et al Mean \pm SD	Yadav AS et al Mean \pm SD
	Males Mean \pm SD	Females Mean \pm SD				
TC	160.09 \pm 25.25	153.51 \pm 33.16	165.7 \pm 30.2	162.85 \pm 30.699	162.5 \pm 22.6	172.08 \pm 26.80
TG	129.07 \pm 45.87	129.88 \pm 51.43	88.36 \pm 31.2	102.93 \pm 27.984	94 \pm 23.5	100.88 \pm 18.26
HDL-C	40.35 \pm 13.04	47.84 \pm 14.30	44.86 \pm 10.68	43.45 \pm 10.759	40.1 \pm 8	47.51 \pm 14.53
LDL – C	84.56 \pm 32.32	87.90 \pm 27.32	101.66 \pm 29.8	98.67 \pm 27.567	103.8 \pm 22.2	110.29 \pm 24.79
VLDL- C	28.31 \pm 16.48	30.53 \pm 24.68	18.11 \pm 7.35	20.78 \pm 5.563	18.3 \pm 4.8	19.74 \pm 3.87

Lipid profile values in healthy controls are reported in earlier studies. Yadav AS et al⁷ worked on relationship of plasma homocysteine with lipid profile parameters in ischemic heart disease and Bhagwat VR et al⁸ worked on homocysteine, lipid indices and antioxidants in patients with ischemic heart disease from rural India. The results were comparable to the present study. Madhumita Das et al⁹ reported on reference interval of lipid profile in a larger sample of Assamese population. Their study included 1485 apparently healthy Assamese in a wider age group of 20-80 years from the urban area of Assam. There was no significant difference according to age and sex. Median and upper range of TC, HDL-C and LDL-C were found to be higher in women than in men in all the age groups. But TG and VLDL-C concentrations were observed higher in the men than women except in age group of 61-70 years. Pushpa Durgawale et al¹⁰ studied reference intervals of serum lipid profile from 914 healthy populations in western Maharashtra. Their study reveals that there were no appropriate differences according to the age and sex between most of the groups. They found low TG and high HDL-C in female as compared with male of same age group. Yuthika Agrawal et al¹¹ studied reference values of lipid profile of 120 healthy subjects attending a premier tertiary hospital in Haryana. They studied lipid profile and compared these values with the internationally recommended ranges. In this study it was found that the upper limits of the reference range of the lipid profile parameters were higher than manufacturer's reference values. Venkataraman D. et al¹² studied lipid profile of 1245 healthy subjects of middle district of Southern Tamil Nadu. According to their study the mean values of TC, TG, LDL-C were increased, while HDL-C level was decreased with the age. However, TC and LDL-C was found to be increased in women having age above 60 years. Yadav D. et al¹³ studied reference interval for lipid profile of North Indian individuals from Rajasthan in age group 15 to 60 years. According to their studies no difference was observed between male and female as well as vegetarians and non-vegetarians in TC, TG and LDL-C levels.

However HDL-C was higher in female as compared to male. There was no marked difference in reference interval of these parameters in rural and urban populations.

In the present study total 554 (330 males and 224 females) samples were estimated for lipid profile parameters. The serum TC levels in males were 160.09 ± 25.25 mg/dl with maximum values was 205mg/dl whereas in females it was 153.51 ± 33.16 mg/dl with maximum values was 200.3 mg/dl. The mean serum TC was found non-significant when compared males with female values ($P > 0.05$). In the present study it was found that females were having low levels of TC as compared with males. However it was non-significant. The exact mechanism for such change is not known but may be attributed to hormone estrogen. The serum TG levels in males were 129.07 ± 45.88 mg/dl whereas in females it was 129.88 ± 51.43 mg/dl. The mean serum TG was found non-significant as compared males and females ($P > 0.05$). The serum HDL-C levels in males were 40.35 ± 13.04 mg/dl whereas in females it was 47.85 ± 14.30 mg/dl. The mean serum HDL - C was significantly higher ($P < 0.05$) in females as compared to males (Table No.1). These higher values of HDL - C in females may be because of altered estrogen levels in female, which increases HDL- C levels. The serum LDL - C levels in males were 84.56 ± 32.32 mg/dl whereas in females it was 87.90 ± 27.32 mg/dl. The serum VLDL - C levels in males were 28.31 ± 16.48 mg/dl whereas in females it was 30.53 ± 24.68 mg/dl. The LDL-C:HDL-C ratio in males it was 2.33 ± 0.93 whereas in females it was 2.17 ± 0.97 (Table No. 1). The serum LDL - C, VLDL - C and LDL-C: HDL-C Ratio was found non-significant when compared to males and females. We have compared our lipid profile data with previous workers from different region of India (Table No. 3). A reference interval for each parameters were calculated from the 95% reference intervals ranging from 2.5% and 97.5% percentiles and, arithmetic mean ± 2 SD were also calculated. Our results of lipid profile parameters were comparable with previous workers⁷⁻¹³. The classification of lipid profile was done as per recommendations of National Cholesterol Education Program

(NCEP) and Adult Treatment Panel III (ATP III) guidelines¹⁴. According to this classification desirable level of TC was <200 mg/dl, borderline high was between 200-239 mg/dl and high TC was considered when the level was > 240 mg/dl. TG level was considered normal when it was <150 mg/dl, borderline high TG was between 150-199 mg/dl, between 200-499 mg/dl was considered high TG and very high TG was defined when it was >500 mg/dl. Similarly optimal level of LDL - C was defined when it was <100 mg/dl, near optimal level was between 100-129 mg/dl, borderline high was between 130-159 mg/dl, the level was considered high when it was between 160-189 mg/dl. When LDL- C level was >190 mg/dl then it was defined very high, according to the guideline¹⁵. We have categorized distribution of lipid profile values of healthy controls from rural population of Konkan region of Maharashtra state as per National Cholesterol Education Program (NCEP) and Adult Treatment Panel III classification¹⁴. It was found that more than 80% of healthy controls from both gender fall in

desirable levels or normal levels and less than 20% were in normal but they were in borderline high levels (Table No.2). Our values of lipid profile parameters in the normal healthy controls in both gender were agreeable and within the acceptable range as suggested by National Cholesterol Education Programme^{14,15}.

CONCLUSION

In clinical laboratory setup the diagnosis, monitoring the disease process and prognosis of disease is dependent on the patient's reports. Therefore it is necessary for every laboratory to establish their own reference intervals of every parameters because the levels varies with age, gender, region, dietary patterns and physical activities. In the present study reference values of lipid profile were obtained from rural area of Konkan region of Maharashtra state It will be useful for clinicians for clinical evaluation of patients from rural area of Konkan region of Maharashtra state.

ABBREVIATIONS

TC: Total Cholesterol, TG: Triglycerides, HDL-C : HDL- Cholesterol, LDL-C : LDL-Cholesterol, VLDL-C: VLDL Cholesterol.

CONFLICT OF INTEREST

Conflict of interest declared none.

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