Original Research Article

Establishment of Reference Intervals for Fasting and Non- fasting Serum Lipid Profile from Healthy Population

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Abstract

Background: A lipid profile is a combination of blood tests performed to check the cholesterol levels and the level of triglycerides in the blood. High cholesterol is linked to heart diseases, obesity, diabetes, etc. Those who are at a higher risk of these conditions or have been diagnosed with these issues need to undergo a lipid profile. Various factors affect lipid profile parameters like age, ethnicity, diet, genetic and gender differences and this makes is essential to establish a reference range of the values of serum lipids for specific population in India. This study was done to evaluate the reference values of lipid profile of a sub urban South Indian population as per the guidelines of the National Cholesterol Education Program (NCEP) of the USA. Reference values used in most of the laboratory are based on the western population in most laboratories and they do not have any similarity with the Indian population, because of many variables and this applies more specifically in case of the lipid profile. These western studies based reference values are used by almost all clinicians worldwide, to interpret the results obtained in patients, it should correctly represent the defined population having close comparison with the patient coming for investigation. As very less documented evidence on establishment of reference levels for lipids parameters for the Indian population, so there is a need for large scale study on lipid profile of Indian population. **Materials and methods:** A cross-sectional study, including 200 subjects in total (according to CLSI guidelines) were analyzed in fasting and non fasting states for the same patient, for total cholesterol, triglycerides, HDL-cholesterol by standard methods and, LDL-cholesterol was calculated using Friedewald's formula. Results: After analysis, Mean values and ranges(2.5–97.5th percentile) in mg/dL for fasting and nonfasting TC, TG, VLDL, LDL-C ,HDL-C were: 110-240 , 39.2 - 174.2, 57.2 - 172.0, 8.0 - 42.0, 32-72.0 in fasting and 116.2 - 252.2, 44.0 - 280.2, 52 - 180.2, 8.6 - 56.2, 26-68.0 in non fasting respectively . After grouping them according to age and sex, we observed that HDL-C was significantly wider in females compared to males, TC was not significantly wider, but TG was higher in males. In the age group 46-55 years TC, TG, HDL-C and LDL-Cholesterol in males were higher as compared to females of that age group.**Conclusion:** Reference ranges are wider as compared to western standard, which is due to variation in diet, ethnicity, environment, etc. Hencethis can be considered as the reference interval for this study population, further study is needed in a larger population.

Keywords: HDL-C, LDL-C, Lipid profile, Reference interval, Total cholesterol, Triglyceride.

Introduction

Health is conceptually different in different countries, in the same country at different times and in the same individual at different ages. It is thus a relative or absolute state. This means that the condition of individuals must be related to or compared with reference data. It is thus the central role of the laboratory scientist to aid the clinician in interpreting the observed values by providing the relevant reference values and presenting them in a convenient and practical form[1].

Clinicians compare thepatient related observation with the reference values and come to a conclusion on the diagnosis of the disease, which help them to treat the patient accurately[2].

A reference interval may be the range of values that are deemed normal for physiological measurement of a particular type of quantity in a reference population[3].

The concept of reference interval was introduced by International Federation of Clinical Chemistry (IFCC) to avoid the problems with normal values and values obtained from an individual under clinical investigations.

According to IFCC, it is necessary for every laboratory to have its own set of reference limits. 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 noted in case of lipid profile. In clinical chemistry, the use of the term lipids generally refers to lipoprotein metabolism and atherosclerosis, a cause of coronary heart disease (CHD).

The central role of the laboratory scientist is to aid the clinician, in interpreting observed values, by providing relevant reference values in a convenient and practical form[4].

In India, reference values used in laboratories have been established in the western population,; these usually do not match with the Indian population especially noted in case of lipid profile. Reference values may be used to evaluate the state of health of individuals and populations, to identify people at risk for disease, to help in decision making in clinical medicine and to be used for various scientific purposes.

Reference intervals are established by collecting specimens and analysing from a sample group of people who meet carefully defined criteria[2].

To establish a reference interval for a general population is a major challenge, as it requires selecting the appropriate reference population and recruiting individuals who represent relevant demographic groups that meet the inclusion criteria; collecting, processing and testing specimens; and finally, calculating reference values with possible stratification of the data into subgroups.

Available global data have clearly established the relationship of lipids and other risk factors with cardiovascular and cerebrovascular events.

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To establish a reference range of the values of serum lipids for a given population is necessary, as only a few studies have been carried out in other regions of India[5,6,7,8,9].

Lipids are a heterogeneous group of fat and fat soluble substances characterized by being water-insoluble and soluble innonpolar solvents such as alcohol, ether, chloroform, benzene, etc.

Lipoproteins are lipid–protein complexes in which lipids are transported in blood. There is a great variation of plasma lipid levelsin different populations and are usually affected by age, sex, food habits, lifestyle, socioeconomic status, races, heredity, etc.

Lipids and lipoproteins are intimately involved in the development of atherosclerosis, which is the underlying cause of cardiovascular disease like myocardial infarction. It can also cause cerebrovascular disease and peripheral vascular disease.

Usually the lipid profile is done in fasting blood specimen, due to two main reasons:

Postprandial triglycerides remain elevated for several hours after meals and are highly variable.

The reference values for serum lipid profile have been determined on fasting blood specimen. People mainly live in the non-fasting state during a regular 24-hour cycle. Therefore, non-fasting lipid panels may be a reliable indicator of average lipid concentration level because the fasting state only occurs after fasting for at least 8 hours. The advantage of non-fasting over fasting lipid measurements is a simplified blood collection process for patients and physicians that is suitable for children, the elderly, and diabetic patients.

Numerous clinical trials have shown that non-fasting low-density lipoprotein cholesterol (LDL-C) has prognostic value that is similar to fasting levels. Non- fasting triglyceride (TG) levels are associated with an increased risk of coronary heart disease (CHD), similar to the increased risk associated with fasting concentrations.

This observation has led to the notion that non-fasting lipids may be an equivalent or better predictor of cardiovascular conditions since non-fasting lipid profiles can reflect real status of circulating lipids.

Non-fasting lipid measurements are not “universally applicable”, and may require additional fasting lipid testing under certain clinical conditions. First, an additional laboratory test is required if non-fasting samples are initially analyzed for glucose or therapeutic drug monitoring. Second, the European consensus has recommended that laboratories offer re-measurement of fasting TGs if non-fasting TG levels are ≥350 mg/dL, because TG concentrations are more stable in the fasting state[10]. Additionally, patients recovering from hypertriglyceridemia-induced pancreatitis or with diagnosed hypertriglyceridemia (TG ≥200 mg/dL according to American Heart Association guidelines) should be assessed fasting lipids during clinic follow-up . Finally, medications that can cause hypertriglyceridemia may affect non-fasting lipid profiles, thus emphasizing the need for repeated fasting measurements[11].

The impact of lipid-lowering medications on non-fasting lipid profiles has not been thoroughly evaluated. Statins, the most widely used lipid-lowering drugs, are known to reduce LDL-C by up to 50% and decrease TGs by 20%.

Although non-fasting samples have been collected in several clinical trials following statin therapies , little information is currently available regarding differences between fasting and non-fasting lipid measurements in statin-treated individuals[12,13].

Fasting for >8 h, as previously required for lipid profiles, normally only occurs a few hours before breakfast. By contrast, the nonfasting state predominates most of a 24-h cycle and better captures atherogenic lipoprotein levels. Plasma contains atherogenic lipoproteins of hepatic origin in the fasting state and additionally those of intestinal origin in the nonfasting state[14].

Maximal mean changes for random, nonfasting versus fasting levels are +26 mg/dl for triglycerides, -8 mg/dl for total cholesterol, -8 mg/dl for low- density lipoprotein cholesterol, +8 mg/dl for remnant cholesterol, and -8 mg/dl for non-high-density lipoprotein cholesterol; lipoprotein(a), apolipoprotein B, and high-density lipoprotein cholesterol are largely unaffected[15].

For patients, laboratories, and clinicians alike, nonfasting lipid profiles represent a simplification without negative implications for prognostic, diagnostic, and therapeutic options for cardiovascular disease prevention.

Several societies' guidelines and statements in Denmark, the United Kingdom, Europe, Canada, Brazil, and the United States endorse nonfasting lipid profiles.

Non-HDL-C was calculated as TC minus HDL-C, equivalent to the combined LDL-C, remnant cholesterol, and lipoprotein(a) cholesterol. Calculated LDL-C was defined by Friedewald equation as follows: LDL-C (mg/dL) = TC (mg/dL) − HDL-C (mg/dL) − TG (mg/dL)/5. The differences of lipid panels were calculated as follows: (non-fasting − fasting)/fasting ×100%[16].

Before 2009 essentially all societies, guidelines, and statements required fasting before measuring a lipid profile for cardiovascular risk prediction. This was mainly due to the increase seen in triglycerides during a fat tolerance test. However, individuals eat much less fat during a normal day and nonfasting triglycerides have been shown to be superior to fasting in predicting cardiovascular risk[17]. Lipids and lipoproteins only change minimally in response to normal food intake: in four large prospective studies, maximal mean changes were +0.3 mmol/L (26 mg/dL) for triglycerides, -0.2 mmol/L (8 mg/dL) for total cholesterol, -0.2 mmol/L (8 mg/dL) for LDL cholesterol, and -0.1 mmol/L (4 mg/dL) for HDL cholesterol.

Further, in 108,602 individuals from the Copenhagen General Population Study in random nonfasting samples, the highest versus the lowest quartile of triglycerides, total cholesterol, LDL cholesterol, remnant cholesterol, non-HDL cholesterol, lipoprotein(a), and apolipoprotein B were all associated with higher risk of both ischaemic heart disease and myocardial infarction[18].

Finally, lipid-lowering trials using nonfasting blood samples for assessment of lipid levels found that reducing levels of nonfasting lipids reduced the risk of cardiovascular disease. To date there is no sound scientific evidence as to why fasting should be superior to nonfasting when evaluating a lipid profile for cardiovascular risk prediction. Indeed, nonfasting samples rather than fasting samples have many obvious advantages.

First, it would simplify blood sampling in the laboratory. Second, it would benefit the patient, avoiding the inconvenience of fasting and therefore needing to have blood drawn early in the day. Third, for individuals with diabetes, the risk of hypoglycaemia due to fasting would be minimised.

Many countries are currently changing their guidelines towards a consensus on measuring a lipid profile for cardiovascular risk prediction in the non fasting state, simplifying blood sampling for patients, laboratories, and clinicians worldwide[19].

Commonly the reference values used in most of the laboratoryare based on the western population. These usually do not have similarity with the Indian population; this is seen especially in case of the lipid profile. Clinicians all over the world uses these reference values to interpret the results obtained in patients, it should correctly impersonate the defined population having close comparison with the patient coming for investigation.

There is no well documented evidence for the establishment of reference levels for lipids parameters for the Indian population, so there is a need for large scale study on lipid profile of Indian population.

Aim & Objectives

To establish the reference intervals for lipid profile for Fasting and Non fasting samples in a semi-urban population.

Materials & Methods

Total of 200 subjects were included in the study (according to CLSI guidelines to establish the reference intervals) in a private clinical diagnostic laboratory setup, Siddipet, Telangana over a period of 6 months.

Inclusion Criteria

Normal healthy individuals aged between 18 years and 55 years with body mass index (BMI) between 18 kg/m2 and 25 kg/m2.

Exclusion Criteria

Patients with cardiovascular disease, diabetes mellitus, hypertension, malnutrition, renal diseases, cerebrovascular diseases, sepsis, medications, TPN, alcohol abuse, smoking, endocrine disorders, pregnancy, various storage disorders, congenital biliary atresia, dyslipidemia, obesity, strenuous exercise, HRT.

A. Exclusion criteria based on history and clinical examination for defining reference individuals

Diabetes mellitus	Excessive body weight
Dyslipidemias	Smoking
Hypertension	Alcohol abuse
Cardiovascular disease	Pregnancy
Medication	Strenuous exercise

Methods

Anthropometric measurements: height was measured in centimeters without shoes by standard procedure and weight was measured in kilograms and used for calculation of BMI.

Method of sample collection

A 2 mL of blood sample was collected from seated subjects from the antecubital vein with aseptic precautions with 2cc syringe in plain red-topped vacutainer tubes containing clot activator. We collected two samples from each individual, one sample was collected after 8–12 hours of fasting and second sample was collected in nonfasting state (i.e., random sample).

We separated the serumby centrifugation at 3,000 rpm for 5 minutes within 1 hour andlipid profile parameters were assayed in duplicate to minimize analytical variation in Roche Hitachi (902) autoanalyzer.

Quality control: The clinical chemistry analyzer was calibrated with materials provided by the Bio-Rad. Changes in calibration curve and specificity of the analytical method were detected by using anumber of accuracy control specimens, at both normal (levelI) and pathological (levels II) of concentration, for the lipid profile analytes. During the study there were no change in the equipment, reagents, calibration standards, and controls.

The following parameters were analyzed by these specific methodologies:

1. Cholesterol by CHOD-PAP method
2. Triglycerides by glycerophosphate oxidase method
3. HDL-cholesterol by direct/homogeneous assay
4. LDL-cholesterol was calculated using Friedwald's formula 20

Serum total cholesterol was measured by enzymatic CHOD–PAP method with lipid clearing agent using cholesterol esterase, cholesterol oxidase and peroxidase.

High density lipoprotein cholesterol was measured by a homogeneous method for directly measuring HDL-C levels in serum without the need for any off-line pre-treatment or centrifugation steps.

Serum triglycerides were measured with an enzymatic colorimetric method involving lipoprotein lipase, glycerol kinase, glycerol-3-phosphate oxidase and finally in the presence of peroxidase (POD), hydrogen peroxide oxidizes aminoantipyrine and N-ethyl-N-(2-hydroxy-3-sulfopropyl)-3-methylaniline into a red compound. VLDL and LDL were calculated using Friedewald's formula

Non-HDL-C was calculated as TC minus HDL-C, equivalent to the combined LDL-C, remnant cholesterol, and lipoprotein(a) cholesterol. Calculated LDL-C was defined by Friedewald equation as follows: LDL-C (mg/dL) = TC (mg/dL) − HDL-C (mg/dL) − TG (mg/dL)/5. The diff(%)s of lipid panels were calculated as follows: (non-fasting − fasting)/fasting ×100%.

Statistical analysis

SPSS version 17 was used Mean ± SD was calculated –97.5th percentiles were calculated.Total cholesterol, LDL-C were calculated by parametric method to determine the 2.5– 97.5th, triglyceride, HDL-C, VLDL were calculated by nonparametric method-based Mann–Whitney's ranked data Comparison between male and females was done using student"t" test p value < 0.05 is taken as significant.

Results

Mean values and ranges(2.5–97.5th percentile) inmg/dL for fasting and nonfasting TC, TG, VLDL, LDL-C ,HDL-C were: 110-240 , 39.2 - 174.2, 57.2 - 172.0, 8.0 - 42.0, 32-72.0 in fasting and 116.2 - 252.2, 44.0 - 280.2, 52 - 180.2, 8.6 - 56.2, 26-68.0 in non fasting respectively as shown in Table 1 and Figure 1.

According to age and sex, it was observed that the referencerange for HDL-C was significantly wider in females when compared to males, reference range for TC was wider but not significant, butTG was higher in males as shown in Tables 2 and 3 and Figure 2.

In the age group 46–55 years TC, TG, HDL-C and LDL-C were higher in males as compared to females of that age group (datanot shown).

Table 1: Mean levels of distribution for both males and females

Sex	N (number)	%
Male	128	64%
Female	72	36%
Total	200	100%

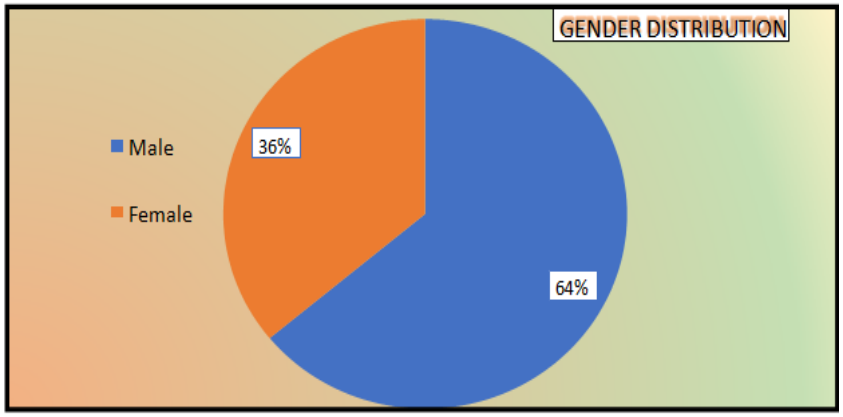

Figure 1: Mean levels of distribution for both males and females

Table 2: Age wise distribution of the subjects

Age Group	Male	Male %	Female	Female %	Total	Total %
18-30 YRS	20	15.6%	11	15.3%	31	15.5%
31-45 YRS	46	35.9%	38	52.8%	84	42.0%
46-55 YRS	62	48.4%	23	31.9%	85	42.5%
Total	128	100.0%	72	100.0%	200	100.0%

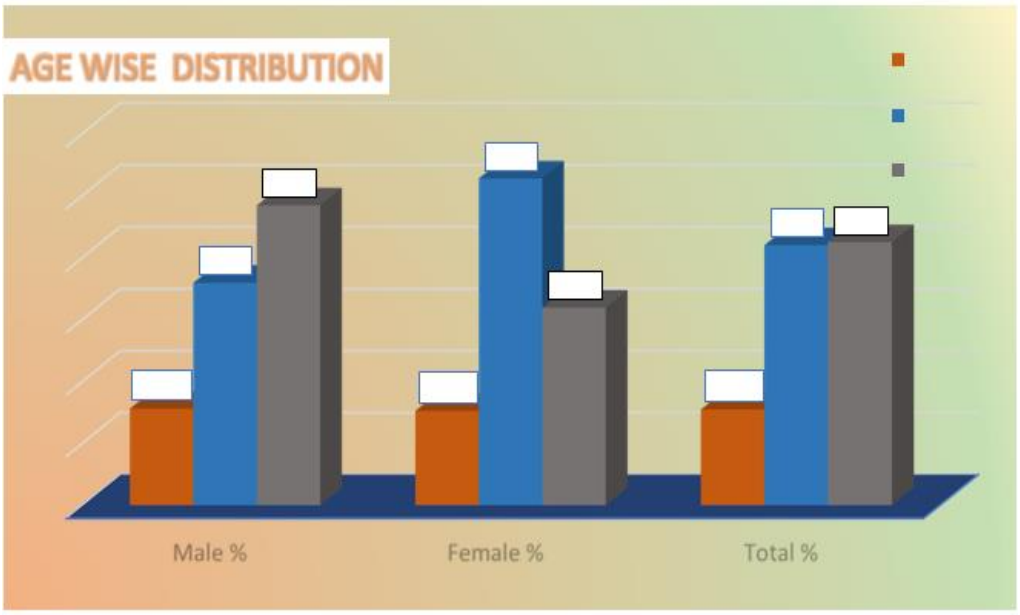

Figure 2: Age wise distribution of the subjects

Table 3: **Reference ranges for fasting and non fasting lipid profile obtained inour total study population**

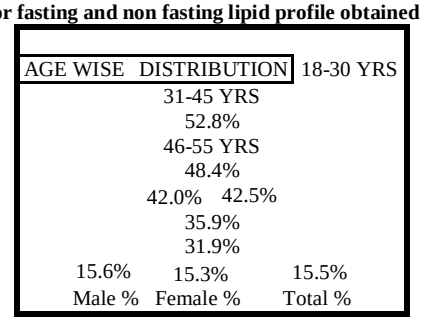

Table 4: **Mean values for fasting and nonfasting lipid profile obtained in ourtotal study population**

Reference ranges for fasting and nonfasting lipid profile obtainedin our total study population					
	TC	TG	LDL	VLDL	HDL
Reference interval (fasting lipidprofile)	110-240	39.2 - 174.2	57.2 - 172.0	8.0 - 42.0	32-72.0
Reference interval (nonfasting lipid profile)	116.2 - 252.2	44.0 - 280.2	52 - 180.2	8.6 - 56.2	26-68.0

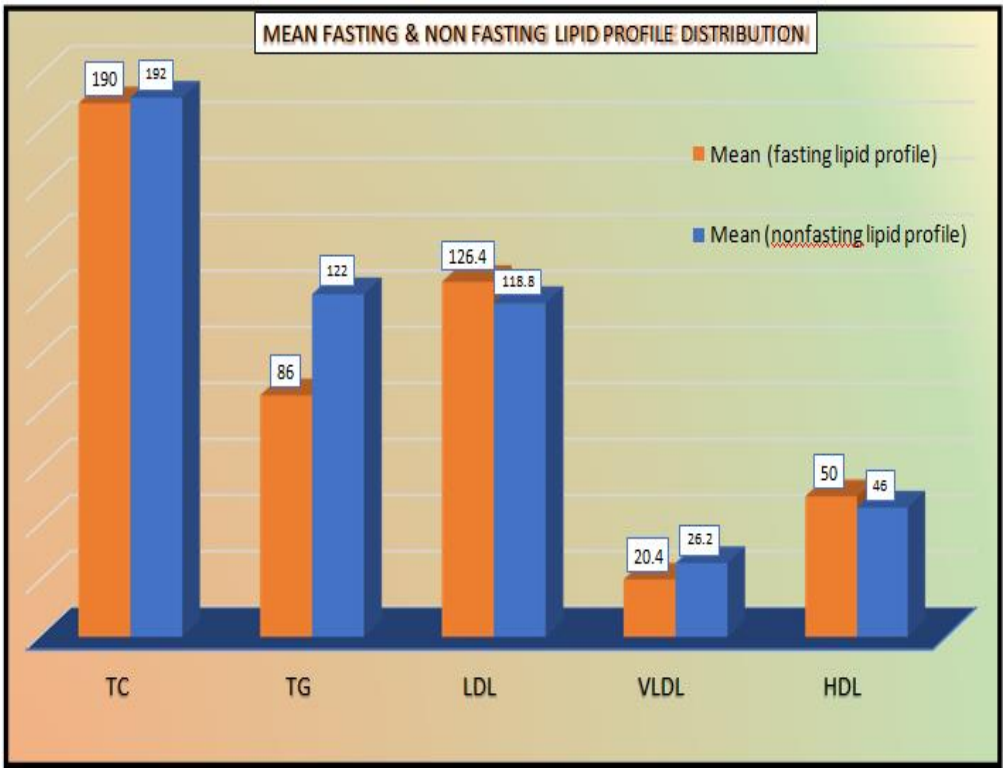

Figure 3: Mean values for fasting and non fasting lipid profile obtained in ourtotal study population

Table 5: Reference ranges for fasting and non fasting lipid profile obtained inour total study population in the age groups.

Mean values for fasting and nonfasting lipid profile obtained in our total study population					
	TC	**TG**	**LDL**	**VLDL**	**HDL**
Mean(fastinglipid profile)	190	86	126.4	20.4	50
Mean (nonfasting lipid profile)	192	122	118.8	26.2	46

Table 6: Mean values for lipid profile obtained in our total study population

Reference ranges for lipid profile obtained in different age groups in ourstudy population						
Age (years)	**No. of participants (n)**	**TC**	**TG**	**LDL**	**VLDL**	**HDL**
18-30 YRS	31	106-200	28-158	44-158	5.4-38.2	36-73.2
31-45 YRS	84	134-236	42-168	70-194.2	8-58.2	30-74
46-55 YRS	85	130-250	36-208	66-184	7.6-46	27.2-68.2

Mean values for lipid profile obtained in different age groups in our study population					
Age (years)	**TC**	**TG**	**LDL**	**VLDL**	**HDL**
18-30 YRS	180	80	112	16	48
31-45 YRS	198	92	132	20	48
46-55 YRS	212	110	140	24.2	50.2

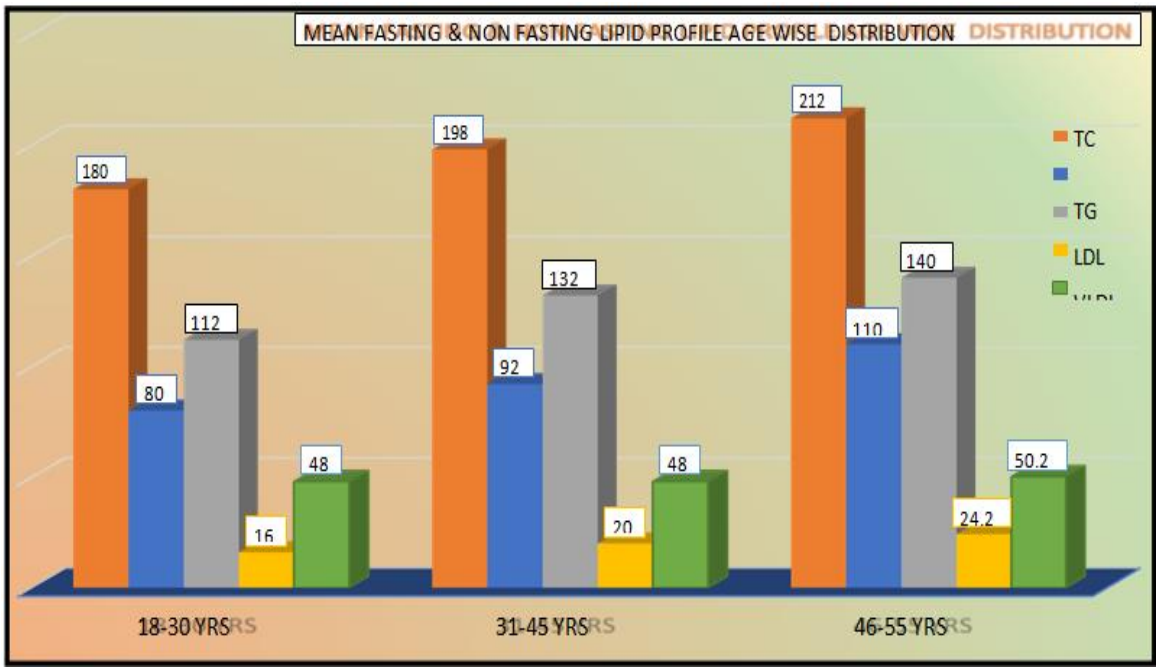

Figure 4: Mean values for lipid profile obtained in our total study population

Table 7: Comparison of reference ranges between males and females

Comparison of reference ranges between males and females					
Lipid profile	**Males (Range)**	**Males (Mean)**	**Females(Range)**	**Females(Mean)**	**p value**
TC	118- 240	186.2	108- 242.2	192	0.26
TG	30.4 - 278.2	108	28 - 200	78	0.001*
LDL-C	60- 180	126.2	60.4 -170.2	126.8	0.051
VLDL	7.8- 44	18.2	8.0 -40.2	46.2	0.001*
HDL-C	33 - 70	44.2	30 - 74.2	50.2	0.001*
*Highly significant *p* value					

Discussion and conclusion

The levels of total cholesterol, LDL-C, HDL-C and serum triglycerides are routinely requested by all the clinicians and so form an important profile in almost all the diagnostic laboratories. The recommended procedure by different authorities like IFCC, NCEP to identify, collect and measure enough samples from a sufficiently large population is not feasible for most laboratories, which thus have to rely on literature data or manufacturers' insert sheets. There is a great variation of plasma lipid levels in different populations and usually are affected by age, sex, food habits, lifestyle, socio– economic status, race, heredity etc[21].

Numerous reports are available in literature relating to serum plasma lipids, lipoprotein (a), apolipoproteins and their subtractions as important risk assessment parameters for atherosclerosis causing cardiovascular and cerebrovascular disorder[22].

Health and disease can be distinguished by accurate and reliablereference intervals of a clinical laboratory testing. Reference interval is crucial for disease screening, diagnosis, monitoring, progression and treatment efficacy. Clinical chemistry reference intervals are also important for identifying abnormal laboratoryresults and ultimately guiding patient management decisions.

Providing relevant reference values in convenient form is the main and important role of the laboratory physician, which willhelp the clinician in interpreting the observed value and make adiagnosis. The reference ranges what we use in most of the Indian laboratories are the one which were established in the western population.

Fasting lipid panels have been the standard in clinical practice for the past half-century since the fasting TG levels were recommended in the 1967 classification of hyperlipidemia[23].

Since then, fasting lipids have been widely used in real-world clinical practice to reduce measurement variability for TG and TC. Although fasting lipids may lead to a more accurate Friedewald-calculated LDL-C, the inconvenience of fasting lipid measurement has decreased patient compliance for lipid analysis.

Recent studies have demonstrated the reliability of non-fasting TG for predicting risk of myocardial infarction, ischemic heart disease, and cardiovascular death, suggesting that non-fasting lipids may be useful for cardiovascular risk prediction[24].

The present study aimed to establish the reference interval forthe semi-urban population of Siddipet, Telangana. Subjects selected were with normal BMI and no major difference in the diet pattern in the overall present population. Major illnesses were ruled out by clinical history.

Present study showed wider range for TC, TG, VLDL and LDL-C,as compared to the standard reference values, but HDL range was similar to standard reference value.

This might be due to different diet, climatic condition and ethnicity of the local population compared to the westernpopulation.

But some Indian studies, Durgawale et al. showed similar results. The values obtained (in mg/dL) for TC, TG, HDL, VLDL and LDL were 165.7 ± 30.2, 88.36 ± 31.2, 44.86 ± 10.68, 101.66 ± 29.8 and 18.11 ± 7.35, respectively[25].

After grouping according to gender and age, the median and the upper range for total cholesterol, HDL-C and LDL-C concentration were higher in women in comparison to men, andtriglyceride and VLDL cholesterol were higher in men than women,except in age group 38–47 years where cholesterol also is higherin males compared to women.

In present study, the reference range for HDL-C is significantly wider in females as compared to males, TC is wider in females but not

significant. The TG, VLDL, and LDL-C values were higher in malesas compared to females. When grouped into different age group,range for TC, TG, VLDL and LDL-C increased as the age increasedexceptinage group 45–55 years, this could be dueto less number ofparticipants in this age group as compared to the other age group.The gradual increase can be explained by the decreased physicalactivity and decreased tolerance to fat intake and LPL activity and decreased clearance.

Madhumita Das and Mauchumi Saikia did a study on the reference values of lipid profile in Assamese population in the age group of 20–80 years and concluded that cholesterol levels werein wider range in all age groups for both sexes than the reference range used in the laboratories. Ranges of TG levels observed in menin 20–60 years age group and women in 30–60 years age groupwere also wider than the reference range used. Ranges of LDL levelswere also wider in all the age groups. The HDL and VLDL rangeswere almost similar to those used in laboratory[3].

In another study when they grouped the study subjects according to the age and sex, they observed that, there were noappropriate differences observed between most of the groups. They also found that triglycerides in females were low and high HDL-cholesterol when compared with male of same age. They also observed that, there was a gradual increase in cholesterol and low-density lipoprotein levels in the women in the age group beyond40 years. Minor difference was observed with dietary pattern[1].

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 30.72-58.10mg/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.

When compared with a similar study done in western Maharashtra, total mean cholesterol level in males (165.7 ± 9.8 mg/dl) and females (165.95 ± 31.93 mg/dl) was similar but less as compared to the present study[25].

Asharvaid et al. also conducted a study in healthy Indian population in 2005 revealing increased total mean cholesterol level in both males (199 ± 37.54 mg/dl) and females (196 ± 36.13 mg/dl) as compared to that in the present study. The increased level of total cholesterol in Punjabi population can be explained by the excessive consumption of ghee in food[2].

Also, the mean HDL-C level was also significantly higher in females ($P < 0.001$) than in males with a fall with advancing age in both males and females. The level of HDL-C in females has also been found to decrease with advancing age (>60 years) in the study done on lipid profile in western Maharashtra[25].

Also, with increasing age, the number of females having HDL-C level lower than the reference range is increasing with maximum in the age group above 70 years. A high HDL-C level in females before the menopausal age probably protects them against atherosclerosis[14].

The overall mean LDL-C level was higher in females (115.2 ± 31.2 mg/dl) than in males (112.6 ± 32.9 mg/dl) but the difference was not significant. High LDL-C levels in females (133.4 ± 34.8 mg/dl) have been seen as compared to males (116.5 ± 27.6 mg/dl) in a similar study done in Kolkata in 2003. On the contrary, the mean LDL-C levels in the study conducted on lipid profile in Andhra Pradesh reveals lower level of LDL-C in females (99.2 ± 30.6 mg/dl) as compared to males (102.4 ± 29.5 mg/dl)[14].

Decade wise analysis also reveals an increase in LDL-C levels with age in both males and females but the change is not significant. Similar changes have also been observed in decade wise analysis of LDL-C levels in Bengali population of Kolkata[26].

Also, the LDL-C levels outside the reference range are increasing with age with maximum in the 4th decade in males and in the 7th decade in females.

To improve patient compliance with lipid testing, it is recommend that the routine use of non-fasting lipid profiles, while fasting sampling may be considered when non-fasting triglycerides >5 mmol/L (440 mg/dL).

For non-fasting samples, laboratory reports should flag abnormal concentrations as triglycerides ≥2 mmol/L (175 mg/dL), total cholesterol ≥5 mmol/L (190 mg/dL), LDL cholesterol ≥3 mmol/L (115 mg/dL), calculated remnant cholesterol ≥0.9 mmol/L (35 mg/dL), calculated non-HDL cholesterol ≥3.9 mmol/L (150 mg/dL), HDL cholesterol ≤1 mmol/L (40 mg/dL), apolipoprotein A1 ≤1.25 g/L (125 mg/dL), apolipoprotein B ≥1.0 g/L (100 mg/dL), and lipoprotein(a) ≥50 mg/dL (80th percentile); for fasting samples, abnormal concentrations correspond to triglycerides ≥1.7 mmol/L (150 mg/dL).

Life-threatening concentrations require separate referral when triglycerides >10 mmol/L (880 mg/dL) for the risk of pancreatitis, LDL cholesterol >13 mmol/L (500 mg/dL) for homozygous familial hypercholesterolaemia, LDL cholesterol >5 mmol/L (190 mg/dL) for heterozygous familial hypercholesterolaemia, and lipoprotein(a) >150 mg/dL (99th percentile) for very high cardiovascular risk.

Nordestgaard BG et al, in their study, recommend that non-fasting blood samples be routinely used for the assessment of plasma lipid profiles. Laboratory reports should flag abnormal values on the basis of desirable concentration cut-points. Non-fasting and fasting measurements should be complementary but not mutually exclusive[24].

Some study indicated lipid levels in their area are different from those reported by other organizations. The 75th percentile is in the normal range according to ATP-III classification, but 97.5th percentiles are above the normal range of the ATP-III class for lipidprofile.

In our study also when considered 75th percentile was muchwithin the normal range as compared to ATP-III class. Compared to the western Maharashtra population mean andSD for lipid profile, our population showed much higher levels ofTC, TG, HDL-C, VLDL and LDL-C. This difference may be because of variation in dietary habits.

More intake of rice and predominantly a nonvegetarian diet compared to the other population may explain the higher TC, TG, VLDL and LDL-C, other factor may be the physical activity. Higher HDL-C can again be due to high intake of fish in diet.

Conclusion

Reference ranges are wider as compared to western standard, which is due to variation in diet, ethnicity, environment, etc. Hence this canbe considered as the reference interval for this study population, further study is needed in a larger population.

Hence, this study suggests that there is requirement for a greater number of studies to establish a reference interval for all the parameters for Indian population.

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