



“ASSOCIATION OF LIPID PROFILE WITH CHOLESTEROSIS IN CHOLELITHIASIS PATIENTS - A HOSPITAL-BASED STUDY”

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ABSTRACT:

Objectives: The objective was to evaluate the prevalence of cholesterosis in cholelithiasis patients in semi urban population and to analyse various biochemical parameters of lipid profile in cholelithiasis patients and find its association and correlation with cholesterosis in cholelithiasis patients.

Materials and methods: Prospective study was carried out on 200 patients of cholelithiasis admitted in hospital. Based on the histopathological examination done, patient was grouped in two groups cholelithiasis with cholesterosis and without cholesterosis. Various parameters of lipid profile were studied in both the groups and association with cholelithiasis was analysed.

Statistical analysis: Data were methodically gathered and assembled and these observations were tabulated. Mean values of the variables were tested against normal ranges. A separate t-test was applied which showed $p < 0.05$ which was considered statistically significant. Data was analysed using IBM SPSS statistics for windows version 29.

Results: out of 200 cholelithiasis patients 57 patients were having cholesterosis (47 were females and 10 were males) and rest 143 was having cholelithiasis without cholesterosis. Females were predominant in both the groups. Among the biochemical parameters, Total cholesterol, TG, LDL, VLDL, TC/HDL levels were significantly increased in subjects having cholelithiasis with cholesterosis as compared to cholelithiasis without cholesterosis. Moreover, HDL and HDL/LDL levels were decreased significantly in subjects having cholelithiasis with cholesterosis compared to cholelithiasis without cholesterics.

Conclusion: The relationship between lipid profile and cholesterosis in cholelithiasis patients conclude that derangement in lipid profile is risk factor of cholesterosis in cholelithiasis patients. Early detection of deranged lipid profile will help in earlier diagnosis of cholesterosis and its management.

Key words: Cholelithiasis, Cholesterosis, Lipid profile, Cholecystectomy

INTRODUCTION

Cholelithiasis also known as gall bladder stone disease is the chronic recurrent hepatobiliary disorder in which stones are formed. These stones are hardened deposits of digestive fluids which results from impaired metabolism of cholesterol, bilirubin and bile acid.^[1] One of the leading causes of abdominal morbidity and mortality worldwide continues to be gallstone disease.^[2] The prevalence of cholelithiasis has been reported as 2-29% in India.^[3] In India, cholelithiasis is more prevalent in females than men.^[4] Additionally, according to estimates from the National Institutes of Health, complications from gallbladder disease and cholelithiasis account for nearly 3,000 fatalities annually.^[5]

Cholesterosis is a benign condition also referred as strawberry gallbladder is defined by hyperplasia of mucous villous with excessive accumulation of esters of cholesterol within epithelial macrophages.^[6] The disorder is typically clinically asymptomatic and infrequently linked to biliary symptoms or idiopathic pancreatitis.^[7] Cholesterosis is more common in cases of cholesterol stones than pigmented stones.^[8]

The etiopathogenesis of cholesterol stall formation is hypersecretion and supersaturation of cholesterol as well as phospholipids and bile salt concentrations, crystal nucleation, dysfunction of gall bladder secretion and absorption, and gall bladder dysmotility.^[9]

In majority of symptomatic cholesterosis, cholecystectomy is regarded as the standard treatment.^[10] Biliary leakage, bleeding, infection, respiratory problems, recurrent surgeries, mortality and bile duct damage are common postoperative consequences of the cholecystectomy.^[11]

Therefore, to reduce this complication and avoid expensive surgical procedures few biochemical tests such as total cholesterol, HDL, LDL, Triglycerides, VLDL, Total cholesterol/HDL and HDL/LDL has been done. This study was proposed to establish an effective and early diagnostic intervention in order to prevent the occurrence of major complications or to avoid surgical treatment which results post cholecystectomy complications. Our study may help in earlier diagnosis and prevention of cholesterosis by dietary modification and lifestyle changes.

Material and Methods

Study design

The study was designed as prospective.

Study group

The study population included 200 patients diagnosed with gall bladder stone disease seeking medical care at the HAHC Hospital, Jamia Hamdard, Delhi.

Duration of study

5 months (from November 2022 to April 2023)

Sample size

Two hundred patients.

Operational definitions

Confirmed cases of cholelithiasis were taken and diagnosis of cholesterosis was made on the basis of histopathological studies of gall bladder and they were grouped into two categories patients having cholelithiasis with cholesterosis and patients having cholelithiasis without cholesterosis.

Consent (informed) was taken from the patients. Our study was approved by the institutional ethics committee. The identity of the subject was not revealed as data has been used in anonymized form.

Baseline data collection

2 ml of blood samples were drawn from the subjects after 10-12 hours of fasting before starting the treatment. The samples were tested for Biochemical investigations i.e. Serum Total Cholesterol (TC), Triglycerides (TG), HDL, LDL, VLDL, TC/HDL and HDL/LDL ratio on the Beckman AU480 Chemistry Analyzer.

Statistical analysis

Data were methodically gathered and assembled. The observations were tabulated and reported as mean standard deviation. Mean values of the variables were tested against normal ranges. A separate t-test was applied which showed $p < 0.05$ which was considered statistically significant. Standard error of the mean was also calculated. Data was analysed using IBM SPSS statistics for windows version 29.

Results

Two hundred patients diagnosed gall bladder stones disease in HAHC Hospital, South Delhi taken in our study.

Demographic characteristics of the study population

out of 200 cholelithiasis patients 167 (83.5 %) were females and 33 (16.5 %) were males. Out of 200 patients of cholelithiasis 57 (28%) were having cholelithiasis with cholesterosis and 143 (72%) were having cholelithiasis without cholesterosis shown in table 1 and figure 1. Also, out of 57 patients having cholesterosis 47 (82.5%) were females and 10 (17.5%) were males shown in table 1 and figure 2. The mean age of the cholelithiasis patients with cholesterosis was found to be 36 ± 1.425 years and cholelithiasis patients without cholesterosis was 41 ± 1.101 years shown in table:1.

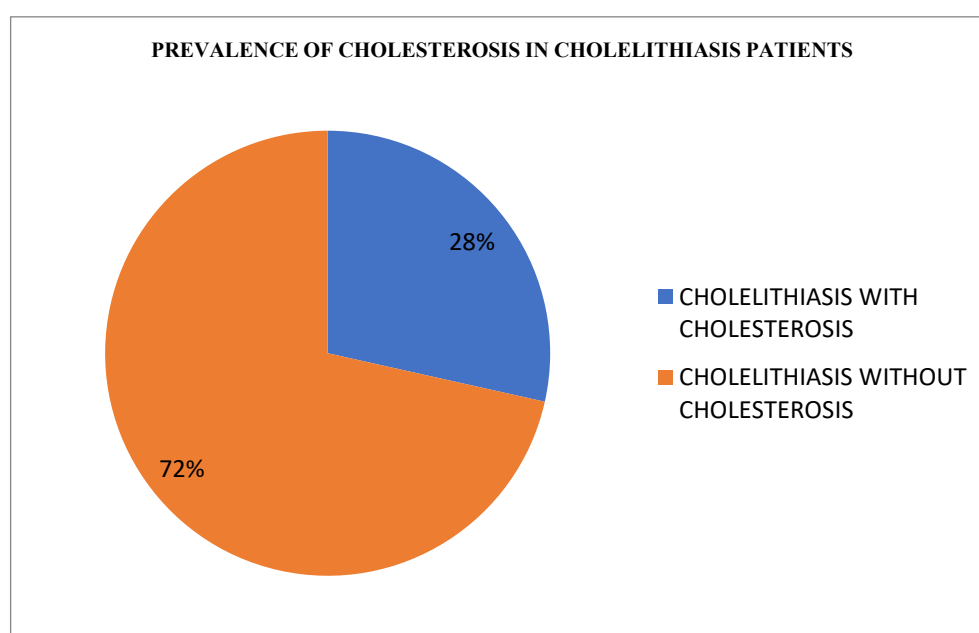


Figure 1: - Prevalence of cholesterosis in cholelithiasis patients

Table 1: Socio Demographic Parameters of the subjects

	Cholelithiasis with Cholesterosis (Mean \pm SEM) (n=57)	Cholelithiasis without Cholesterosis (Mean \pm SEM) (n=143)
Age	36 ± 1.425	41 ± 1.101
Gender Distribution(n)	Male= 10 Female= 47	Male= 23 Female= 120

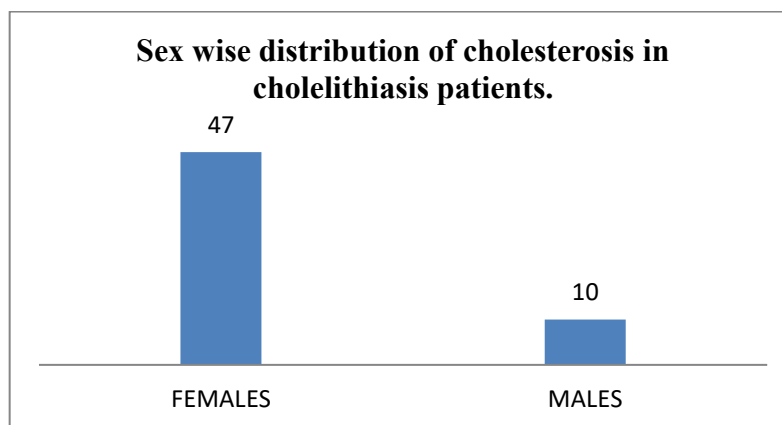


Figure 2:- Sex wise distribution of cholesterosis in cholelithiasis patients.

Clinical profile of study population

All subjects those were taken in this study were diagnosed cases of gall bladder stone disease patients undergoing cholecystectomy.

Laboratory profile of study population

Histopathological study

In gross examination, wall thickness, presence of stones and yellow streak on mucosa was seen. Measurement of the gall bladder was taken then external surface was studied whether unremarkable or congested or bile stone. Neck of the gall bladder was checked for the presence of any stones or lymph node. Then cut section was taken and mucosa was observed for denuded/atrophic /velvety or bile stained. Cut sections were taken from neck and body and fundus.

Microscopy - Histopathological features of cholelithiasis with cholesterosis: Sections from gallbladder showed columnar mucosal epithelial lining. Lamina propria showed collection of foamy macrophages. Wall showed few Rokitansky Aschoff sinus, thickened smooth muscle layer and transmural chronic infiltrate comprising of lymphocytes. Serosa showed dilated and congested blood vessels.

Histopathological features of cholelithiasis with cholesterosis: Minimal / mild lymphocytic mucosal inflammation, Rokitansky-Aschoff sinuses, fibrosis, thickening of muscularis propria, cholesterosis, focal epithelial metaplasia (pyloric / gastric mucin cell metaplasia or intestinal metaplasia)

Biochemical parameters

Among the biochemical parameters shown in table:2 and figure:3 mean value of Total cholesterol was 202.97 ± 4.68 mg/dl in group cholelithiasis with cholesterosis, while the mean was 174.26 ± 2.61 mg/dl cholelithiasis without cholesterosis. Total cholesterol was significantly higher in patients with cholesterosis than without cholesterosis (p value < 0.0001). Mean value of Triglycerides in group cholelithiasis with cholesterosis was 159.2 ± 10.45 mg/dl, while the mean was 120.07 ± 3.62 mg/dl in cholelithiasis without cholesterosis. Triglyceride was also significantly higher in group having cholesterosis than without cholesterosis (p value 0.0007). Mean value of HDL was 43.28 ± 0.94 mg/dl in group cholelithiasis with cholesterosis, while the mean was 47.30 ± 0.63 mg/dl in patients with cholelithiasis without cholesterosis. HDL levels were significantly lower in patients having cholesterosis than without cholesterosis (p value 0.0006). Mean value of LDL was 137.87 ± 4.02 mg/dl in group cholelithiasis with cholesterosis and 109.23 ± 2.03 mg/dl in cholelithiasis without cholesterosis. LDL was significantly higher in patients having cholesterosis than without cholesterosis (p value < 0.0001). The mean value of VLDL was 31.78 ± 2.08 mg/dl in group cholelithiasis with cholesterosis, whereas the mean value was 24.21 ± 0.75 mg/dl in cholelithiasis without cholesterosis. VLDL was significantly higher in patients having cholesterosis as compared to without cholesterosis (p value 0.0011). The mean value of ratio TC/HDL was 4.79 ± 0.13 in group cholelithiasis with cholesterosis, while the mean value 3.73 ± 0.05 in cholelithiasis without cholesterosis. The ratio

TC/HDL was significantly higher in patients having cholesterosis than without cholesterosis (p value <0.0001). The mean value of ratio HDL/LDL was 0.33 ± 0.01 in group cholelithiasis with cholesterosis, while the mean value 0.48 ± 0.03 in cholelithiasis without cholesterosis. The ratio HDL/LDL was significantly lower in patients having cholesterosis than without cholesterosis (p value <0.0001).

Table 2: Comparison of lipid profile between cholelithiasis with cholesterosis and without cholesterosis.

Parameter	Cholelithiasis with cholesterosis Mean \pm SEM	Cholelithiasis without cholesterosis Mean \pm SEM	<i>p</i> -value
TC	202.97 \pm 4.68	174.26 \pm 2.61	<0.0001
Triglycerides	159.2 \pm 10.45	120.07 \pm 3.62	0.0007
HDL	43.28 \pm 0.94	47.30 \pm 0.63	0.0006
LDL	137.87 \pm 4.02	109.23 \pm 2.03	<0.0001
VLDL	31.78 \pm 2.08	24.21 \pm 0.75	0.0011
TC/ HDL	4.79 \pm 0.13	3.73 \pm 0.05	<0.0001
HDL/LDL	0.33 \pm 0.01	0.48 \pm 0.03	<0.0001

TC- Total cholesterol, HDL- High density lipoprotein, LDL-Low density lipoprotein, VLDL-Very low-density lipoprotein.

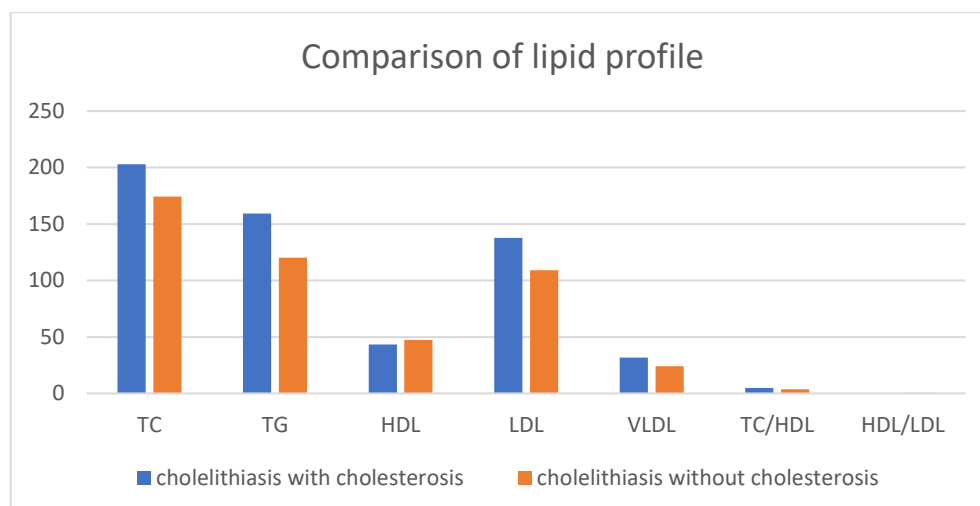


Figure 3:- Comparison of lipid profile between cholelithiasis with cholesterosis and without cholesterosis.

Among the female patients, shown in table: 3 and figure: 4, mean value of Total cholesterol was 202.16 ± 5.26 mg/dl in group cholelithiasis with cholesterosis, while the mean was 174.93 ± 2.79 mg/dl in cholelithiasis without cholesterosis. Total cholesterol was significantly higher in patients with cholesterosis than without cholesterosis (p value <0.0001). Mean value of Triglycerides in group cholelithiasis with cholesterosis was 144.08 ± 7.99 mg/dl, while the mean was 120.21 ± 4.09 mg/dl in cholelithiasis without cholesterosis. Triglyceride was also significantly higher in group having cholesterosis than without cholesterosis (p value 0.0097). Mean value of HDL was 44.02 ± 1.09 mg/dl in group cholelithiasis with cholesterosis, while the mean was 47.71 ± 0.68 mg/dl in patients with cholelithiasis without cholesterosis. HDL levels were significantly lower in patients having cholesterosis than without cholesterosis (p value 0.0054). Mean value of LDL was 136.74 ± 4.51 mg/dl in group cholelithiasis with cholesterosis and 109.34 ± 2.21 mg/dl in cholelithiasis without cholesterosis. LDL was significantly higher in patients having cholesterosis than without cholesterosis (p value <0.0001). The mean value of VLDL was 28.73 ± 1.58 mg/dl in group cholelithiasis with cholesterosis, whereas the mean value was 24.27 ± 0.85 mg/dl in cholelithiasis without cholesterosis. VLDL was significantly higher in patients having cholesterosis as compared to without cholesterosis (p value 0.0153). The mean value of ratio TC/HDL was 4.69 ± 0.14 in group cholelithiasis with

cholesterosis, while the mean value 3.71 ± 0.06 in cholelithiasis without cholesterosis. The ratio TC/HDL was significantly higher in patients having cholesterosis than without cholesterosis (p value <0.001). The mean value of ratio HDL/LDL was 0.34 ± 0.01 in group cholelithiasis with cholesterosis, while the mean value 0.49 ± 0.03 in cholelithiasis without cholesterosis. The ratio HDL/LDL was significantly lower in patients having cholesterosis than without cholesterosis (p value 0.0002).

Table 3: Comparison of lipid profile between cholelithiasis with cholesterosis and without cholesterosis in females

Parameter	Cholelithiasis with cholesterosis Mean \pm SEM	Cholelithiasis without cholesterosis Mean \pm SEM	<i>p</i> -value
TC	202.16 \pm 5.26	174.93 \pm 2.79	<0.0001
Triglycerides	144.08 \pm 7.99	120.21 \pm 4.09	0.0097
HDL	44.02 \pm 1.09	47.71 \pm 0.68	0.0054
LDL	136.74 \pm 4.51	109.34 \pm 2.21	<0.0001
VLDL	28.73 \pm 1.58	24.27 \pm 0.85	0.0153
TC / HDL	4.69 \pm 0.14	3.71 \pm 0.06	<0.001
HDL/LDL	0.34 \pm 0.01	0.49 \pm 0.03	0.0002

TC- Total cholesterol, HDL- High density lipoprotein, LDL-Low density lipoprotein, VLDL-Very low-density lipoprotein.

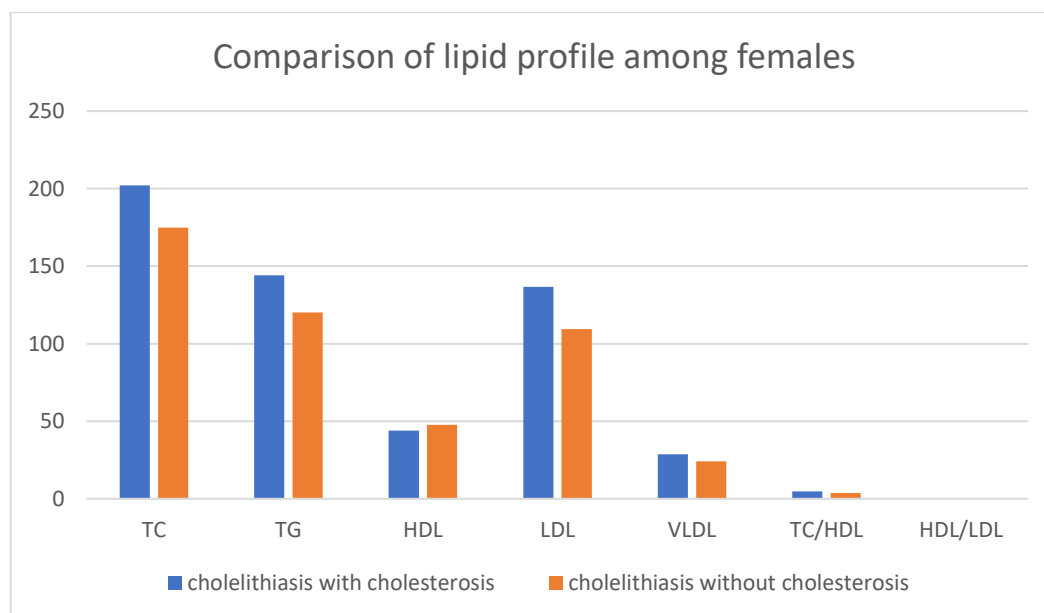


Figure 4:- Comparison of lipid profile between cholelithiasis with cholesterosis and without cholesterosis in females

Among the male patients, shown in table: 4 and figure: 5, mean value of Total cholesterol was 206.8 ± 10.43 mg/dl in group cholelithiasis with cholesterosis, while the mean was 170.76 ± 7.22 mg/dl in cholelithiasis without cholesterosis. Total cholesterol was significantly higher in patients with cholesterosis than without cholesterosis (p value 0.0108). Mean value of Triglycerides in group cholelithiasis with cholesterosis was 230.4 ± 40.70 mg/dl, while the mean was 119.39 ± 7.40 mg/dl in cholelithiasis without cholesterosis. Triglyceride was significantly higher in group having cholesterosis than without cholesterosis (p value 0.0237). Mean value of HDL was 39.83 ± 1.00 mg/dl in group cholelithiasis with cholesterosis, while the mean was 45.18 ± 1.67 mg/dl in patients with cholelithiasis without cholesterosis. HDL levels were significantly lower in patients having cholesterosis than without cholesterosis (p value 0.0100). Mean value of LDL was 143.13 ± 9.04 mg/dl in group cholelithiasis with cholesterosis and 108.77 ± 5.23 mg/dl in cholelithiasis without cholesterosis. LDL was significantly higher in patients having cholesterosis than without cholesterosis (p value 0.0048). The mean value of VLDL was 46.08 ± 8.14 mg/dl in group cholelithiasis with

cholesterosis, whereas the mean value was 23.88 ± 1.48 mg/dl in cholelithiasis without cholesterosis. VLDL was significantly higher in patients having cholesterosis as compared to without cholesterosis (p value 0.0237). The mean value of ratio TC/HDL was 5.21 ± 0.28 in group cholelithiasis with cholesterosis, while the mean value 3.81 ± 0.14 in cholelithiasis without cholesterosis. The ratio TC/HDL was significantly higher in patients having cholesterosis than without cholesterosis (p value 0.0006). The mean value of ratio HDL/LDL was 0.29 ± 0.02 in group cholelithiasis with cholesterosis, while the mean value 0.42 ± 0.18 in cholelithiasis without cholesterosis. The ratio HDL/LDL was significantly lower in patients having cholesterosis than without cholesterosis (p value <0.0001).

Table 4: Comparison of lipid profile between cholelithiasis with cholesterosis and without cholesterosis in males.

Parameter	Cholelithiasis with cholesterosis Mean \pm SEM	Cholelithiasis without cholesterosis Mean \pm SEM	<i>p</i> -value
TC	206.8 \pm 10.43	170.76 \pm 7.22	0.0108
Triglycerides	230.4 \pm 40.70	119.39 \pm 7.40	0.0237
HDL	39.83 \pm 1.00	45.18 \pm 1.67	0.0100
LDL	143.13 \pm 9.04	108.77 \pm 5.23	0.0048
VLDL	46.08 \pm 8.14	23.88 \pm 1.48	0.0237
TC / HDL	5.21 \pm 0.28	3.81 \pm 0.14	0.0006
HDL/LDL	0.29 \pm 0.02	0.42 \pm 0.18	<0.0001

TC- Total cholesterol, HDL- High density lipoprotein, LDL-Low density lipoprotein, VLDL-Very low-density lipoprotein.

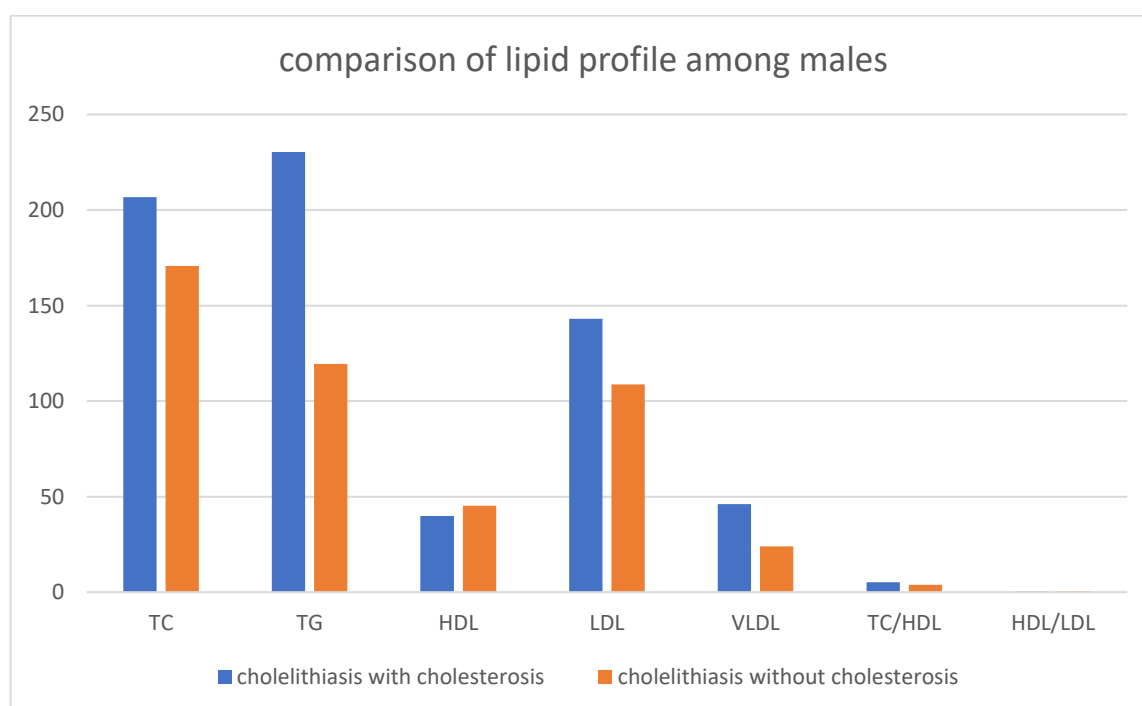


Figure 5:- Comparison of lipid profile between cholelithiasis with cholesterosis and without cholesterosis in male.

DISCUSSIONS

Over the years, there has been an exponential increase in the incidence of cholelithiasis and cholesterosis. The diagnosis of cholelithiasis is currently based on sign and symptoms biochemical examination, radiological examination ultrasonography, and histopathological examination.

This study was conducted in hospital of Delhi which comprises semi urban population of south Delhi. Hence, there is an urgent need for exploration of alternative for earlier diagnosis and monitoring of cholesterosis. Therefore, this study was designed to explore association of lipid profile with

cholesterosis in cholelithiasis patients in semi urban population of south Delhi. This study analysed the parameters of lipid profile which are readily available in semi urban areas.

In our study 200 cholelithiasis patients were taken and categorised into two groups cholelithiasis with cholesterosis and cholelithiasis without cholesterosis. out of which 57(28%) patients of cholelithiasis with cholesterosis and 143 (72%) patients of without cholesterosis were seen. Out of 57 subjects having cholelithiasis with cholesterosis, 47 (82.4%) were females and 10 (17.6%) were males. Out of total female subjects (167), 47 (28.1%) were having cholelithiasis with cholesterosis and 120 (72%) were subjects having cholelithiasis without cholesterosis. Similarly, in males out of 33 males 10 (30%) were having cholelithiasis with cholesterosis and 23 (71.9%) were having cholelithiasis without cholesterosis. Furthermore, our study revealed mean age group in cholesterosis subject was 36 ± 1.425 years whereas mean age group in cholelithiasis patients was 41 ± 1.101 years. Our study also reflected high number of cases of in females (83.5%) compared to males (16.5%). Moreover, higher % of cholesterosis was also seen in females (82.5%) than males (17.5%) The cases of cholelithiasis in female were more may be because of women are more likely to develop cholelithiasis at all stages of life due to naturally increased estrogen levels,^[12] multiparity,^[13] or consumption of estrogen-based oral contraceptives.^[12]

We investigated the different lipid profile parameters between the cholelithiasis group with and without cholesterosis in an effort to establish a correlation between lipid profile and cholesterosis.

In our study it was seen that the mean total cholesterol in patients with cholesterosis was raised above the normal range. Total cholesterol was significantly higher in subjects having cholelithiasis with cholesterosis as compared to without cholesterosis (p value < 0.0001). In females, total cholesterol was significantly higher in group cholelithiasis with cholesterosis than without cholesterosis (p value < 0.0001). Also, in males the similar result was seen that is total cholesterol was higher in subjects having cholelithiasis with cholesterosis as compared to without cholesterosis (p value 0.0108).

Our study also revealed increased serum LDL levels in cholesterosis as compared to subjects without cholesterosis. This came out to be statically significant (p -value < 0.05). Moreover, our study was supported by similar studies done by Han et al. and Fu et al. which showed an association between high serum LDL levels and the formation of cholesterol gallstones.^[14,15] Tang^[16] and Andreotti et al.^[17], on the other hand, found an inverse relationship between the risk of gallstones and serum LDL levels. In females, serum LDL level was significantly higher in group cholelithiasis with cholesterosis than cholelithiasis without cholesterosis (p value < 0.0001). Also, in males the similar result was seen that serum LDL was higher in subjects having cholelithiasis with cholesterosis as compared to cholelithiasis without cholesterosis (p value 0.0048). A high serum LDL level is a sign that a person is more likely to develop cholesterol gallstone disease because LDL more rapidly penetrate into the gallbladder tissue, where the gallbladder wall is intensively captured by macrophages, and participate in the formation of foamy cells.^[18]

Furthermore, our study revealed the serum HDL levels were slightly below normal ranges in cholelithiasis patients. Serum HDL levels in patients with cholesterosis was significantly lower as compared to patients without cholesterosis. This came out to be statically significant (p -value < 0.05). In females, serum HDL level was significantly higher in group cholelithiasis with cholesterosis than cholelithiasis without cholesterosis (p value 0.0054). Also, in males the similar result was seen that is serum HDL level was higher in subjects having cholelithiasis with cholesterosis as compared to cholelithiasis without cholesterosis (p value 0.0100). Moreover, in our study mean serum HDL was lower in males than females. Our results were consistent with an earlier study which showed a positive association between developing cholesterol gallstones and low serum HDL levels.^[14] The most probable reason is that the lower amount of HDL cholesterol is caused by decreased uptake of free cholesterol by HDL from peripheral cell membranes due to impaired complex formation of phospholipid with free cholesterol and associated with altered phospholipid composition of a lipoprotein particle's superficial monolayer. Simultaneously, physicochemical changes in the HDL superficial layer are a cause of abnormal free cholesterol esterification and impaired plunge of esterified cholesterol into the nucleus of an HDL particle, which facilitates HDL to LDL conversion

and may explain elevated LDL levels in cholesterosis. The data imply that serum lipids have a role in the progression of cholesterosis.^[19]

Our study also revealed increased serum triglycerides levels in cholesterosis as compared to subjects without cholesterosis. This came out to be statically significant (p -value 0.0007). Among females, serum triglycerides level was significantly higher in group cholelithiasis with cholesterosis than cholelithiasis without cholesterosis (p value 0.0097). Also, in males the similar result was seen that serum triglycerides level was higher in subjects having cholelithiasis with cholesterosis as compared to cholelithiasis without cholesterosis (p value 0.0237). In our study the mean serum triglyceride levels (230.4 ± 40.70 mg/dl) of male having cholelithiasis with cholesterosis was higher compared to female (144.08 ± 7.99 mg/dl) patients, and this found to be statically significant (p -value < 0.005). But Batajoo H et al. shown triglycerides were not statistically significantly high in patients of cholelithiasis supporting our results.^[20] Saraya A et al. in their study including subjects from north claimed that male patients had greater triglyceride levels.^[21] Similar results as Saraya A et al. came out from our study showed that serum triglycerides are more elevated in males than females in patients having cholesterosis. The increase in serum triglycerides may be because following gallbladder epithelial damage, the ability of the gallbladder to absorb lipids reduces, resulting in an increase in triglyceride levels.

In this study VLDL was found slightly elevated in cholelithiasis with cholesterosis. Serum VLDL levers are significantly elevated in patients having cholelithiasis with cholesterosis than cholelithiasis without cholesterosis (p value 0.0011). Furthermore, in males it is more elevated compared to females in patients with cholesterosis. Among females, serum VLDL level was significantly higher in group cholelithiasis with cholesterosis than cholelithiasis without cholesterosis (p value 0.0153). Also, in males the similar result was seen that is VLDL was higher in subjects having cholelithiasis with cholesterosis as compared to cholelithiasis without cholesterosis (p value 0.0237).

Our study also depicted the ratio Total cholesterol/HDL is significantly higher in patients with cholesterosis than without cholesterosis in cholelithiasis patients (p value < 0.0001). HDL/LDL found to be significantly lower in cholesterosis than without cholesterosis in cholelithiasis patients (p value < 0.0001). similar results were seen in males and females separately.

Limitations of the study

The sample size may have been bigger, but this study paves the path for larger-scale investigations with higher sample sizes.

Conclusion

This study has been undertaken to investigate the relationship between lipid profile and cholesterosis in cholelithiasis patients. Alteration in Lipid profile is the risk factor for occurrence of cholelithiasis and cholesterosis. Early detection of deranged lipid profile will help in earlier diagnosis of cholesterosis and its management. The need of hour is to raise awareness amongst the topic as cholelithiasis have complications such as cholecystitis, pancreatitis, gallstone ileus, biliary tract obstruction. Our study may help in earlier diagnosis and prevention of cholesterosis by dietary modification and lifestyle changes. This will allow timely intervention, ensuring minimum harm and morbidity to the patient in a long run. The disparity in data available from previous sources and paucity of research on this topic in India, especially in the semi urban population, we were inspired to conduct this research.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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