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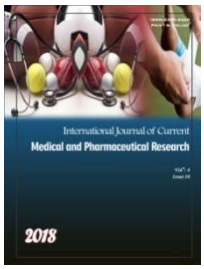

LIVER DISEASES PROFILE AMONG PATIENTS OF METABOLIC SYNDROME IN NORTH EAST INDIA

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ABSTRACT

Background: In the new era of urbanization where world disease burden is rapidly shifting from communicable disease to non-communicable disease, metabolic syndrome (MS) being the prime feature of it, liver diseases related to metabolic syndrome are also in the rise. In western nations nonalcoholic fatty liver disease (NAFLD) is one of the most common causes of chronic liver disease[3, 5, 10] and India is also not far behind from this fate. This present study is designed to evaluate the burden of various liver diseases associated with Metabolic syndrome.
Methodology: Newly diagnosed MS patients are evaluated thoroughly for presence of any liver disease by means of history, clinical examination, and biochemical profile and ultrasonography abdomen findings and further analyzed in details for statistical co-relations.
Results: 60.2% of total study population had underlying liver disease & most of them belonged to older age group (60.8%). In this male dominated study sample (52.8%) a bit higher female preponderance observed (51.4%) in disease prevalence. NAFLD was the most commonly observed hepatic abnormality 34.1% followed by raised transaminases (16.3%) and lastly cirrhosis (NASH related) i.e. 9.8%. Almost all the components of MS were more in the disease group, however BMI, raised total cholesterol level, & lastly low HDL cholesterol level were having significant statistical co-relation with presence of liver disease (<0.05) among the study population
Conclusion: A very high prevalence of liver disease in patients of MS had been observed in this part of the country with NAFLD being the most common spectrum among them.

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INTRODUCTION

Global disease burden is rapidly shifting from communicable to non-communicable diseases due to rural to urban migration, change in economy, lifestyle, behavioral changes, in food habits, and increase in sedentary lifestyle. India is also not quite different. Metabolic syndrome (MS) is the prime character in them. MS (Syndrome X/ Insulin resistance syndrome) consists of a constellation of metabolic abnormalities that confer increased risk of cardiovascular diseases (CVD) & Type 2 Diabetes Mellitus (T2DM)[1].

Features of this syndrome include insulin resistance with associated hyperinsulinemia, impaired glucose tolerance, impaired insulin-mediated glucose disposal, and T2DM; dyslipidemia, characterized by hypertriglyceridemia and low serum high density lipoprotein cholesterol levels; and hypertension [1-2]. Central adiposity is a key component of the metabolic syndrome, the diagnostic criteria of which are based on the recommendations of the National Cholesterol Education Program Adult Treatment Panel III and International Criteria (NCEP: ATP III)[7]. Large number of studies done for prevalence of MS on worldwide population shows highest prevalence among native Americans (nearly 60 % females and 45% males of 45-49 yrs) meeting the criteria of The NCEP: ATP III 2001[1]. Recently studies from Western India showed significantly higher rate of MS in older age group i.e. 9.38% (30-39yrs) vs. 26.98% (60-70yrs) age group & 74% of them had sedentary life style[18]. Another recent community-based study from Eastern India had measured 31.4% MS prevalence with female preponderance (48.2% vs. 16.3%)[12].

Obesity is associated with a spectrum of liver abnormalities known as nonalcoholic fatty liver disease (NAFLD), which is characterized by an increase in intrahepatic triglyceride content (i.e., steatosis) with or without inflammation and fibrosis (i.e., steatohepatitis)[2].

Non-alcoholic steatohepatitis (NASH) is a part of the spectrum of Non-alcoholic fatty liver disease (NAFLD), which encompasses simple fatty liver, NASH, and NAFLD-associated cirrhosis[4]. Steatosis is determined by estimating the proportion of hepatocytes containing fat droplets and suggested lower threshold is 5%. Features of steatohepatitis include hepatocellular injury (ballooning, apoptosis/necrosis, Mallory's hyaline, giant mitochondria), inflammation and fibrosis (perisinusoidal, pericellular)[22-23]. Many centers accept that the maximum allowable level of alcohol intake for

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definition of NAFLD is 2 standard drinks a day (140 g ethanol/week) for men, and one standard drink a day (70 g ethanol/week) for women[24]. The presence of NAFLD is an important marker of metabolic dysfunction in obese persons, independent of BMI, percent body fat, or visceral fat mass [22-24]. The global obesity epidemic has dramatically increased the prevalence of NAFLD, such that it is the most common cause of chronic liver disease in Western nations now [3, 5, 10]. People with NASH are at risk for developing cirrhosis, hepatic decompensation, and hepatocellular carcinoma and have increased all-cause mortality[21]**.** The pathogenesis of NAFLD and the specific steps that lead to NASH and advanced fibrosis are not fully understood, although researchers have found that a combination of environmental, genetic, and metabolic factors lead to advanced disease[21]**.** Subsequent study led to the popular "2-hit" hypothesis by which sequential progression from isolated fatty liver (IFL) to NASH involved an initial lesion of hepatic steatosis followed by a second "hit" of oxidative stress resulting in liver injury[6].

NAFLD has been found to be associated with approximately ~25-60% patients having MS and up to 35% of them have NASH in Western nations [1]. Epidemiological studies from India suggest around 9% to 32% prevalence of NAFLD in general population with higher prevalence in overweight or obese patients and those with diabetes or prediabetes [10]. Studies showed that prevalence of NAFLD in T2DM patients alone in India is as high as 49%[11].

Various epidemiological studies across the world showed that NAFLD & MS are associated with raised alanine aminotransferase (ALT) & aspartate aminotransferase (AST)[15, 16]. Although liver biopsy is currently the gold standard for diagnosis of NAFLD, it can be diagnosed early by noninvasive ultrasonography[19].

Published literatures on NAFLD from India are sparse. This may be related to (i) the fact that the condition was recognized fairly recently, (ii) a presumption that the condition is benign and has a non-progressive course, (iii) a large burden of viral hepatitis in India tends to reduce the priority accorded to this condition[10].

In a country like India where incidence of metabolic syndrome is increasing at a rate in which very few diseases have so far done specially over the Northern India in the face of rapid industrial growth & urbanization, North-Eastern zone of India with its population diversity (tribal and non-tribal) is still untouched. The associations of metabolic syndrome with various liver diseases such as NAFLD which forms the heart of this study is but a serious story that remains buried deep down the mysteries of human body and unfortunately is not so much focused upon otherwise. This present study aimed at evaluation of patients of metabolic syndrome for the presence of liver diseases, its prevalence that likely to offer at least a portion of knowledge regarding the burden of various associated liver diseases along with MS & associated clinic-biochemical profile in this part of the country and will be a useful tool for further reference in near future.

METHODOLOGY

A total 123 newly diagnosed metabolic syndrome patients between 18-70 years of age as per NCEP: ATP III criteria attending Agartala Government Medical College & G.B.Pant Hospital, Agartala, Tripura over a period of one and half year from January 2016 to June 2017 were included in this observational cross-sectional study.

NCEP: ATP III Criteria (2001)[1, 7]

Metabolic syndrome: presence of three or more following criteria

- Waist circumference: ≥102cms for male, ≥ 88cms for female.
- Fasting blood sugar ≥ 110 mg/dl or previously diagnosed T2DM or on specific medication.
- Hypertension by means of ≥ 130 mmHg systolic blood pressure (SBP) or ≥ 85 mmHg diastolic BP or on specific medication.
- Hypertriglyceridemia by means of triglyceride ≥ 150 mg/dl, or on specific medication
- HDL-C < 40 mg/dl in men & < 50 mg/dl, or on specific medication in women

Criteria remained the same for Asia Pacific population except that a waist circumference of ≥ 90 cm in men & ≥ 80 cm in female had been taken as cut off in this study[20]. Cut off BMI (Body Mass Index): **>** 23 and < 25 kg/m^2 for overweight and ≥ 25 Kg/m^2 for obesity respectively was taken as per Asia Pacific Guidelines & was implemented to define the study population[29]. Clinical data were collected from personal interview and systemic examination of each subject. Cut-off level of alcohol intake was taken up to 2 standard drinks a day (140 g ethanol/week) for men, and one standard drink a day (70 g ethanol/week) for women in the study[24].

18-70 years non-alcoholic, hepatitis B & C nonreactive, willing to participate in the study were included in the study whereas people having known liver diseases, ethanolic, <18yrs or >70yrs, having decompensated liver disease and not willing to participate were excluded from the study.

After obtaining written and informed consent from each and every study subjects, proper anthropometric measurements had been taken by standardized instruments and blood samples were drawn for liver function testing [total billirubin, AST, ALT, ALP, GGT (γ-glutamyl transpeptidase), total protein, albumin and globulin], fasting (FBS) and post-prandial blood sugar (PPBS) level and for lipid profile testing [total cholesterol(TC), triglycerides(TGs), low density lipoprotein cholesterol(LDL-C), high density lipoprotein cholesterol(HDL-C), very low density lipoprotein cholesterol(VLDL-C)]. Hepatitis B virus surface antigen detection and antibody against Hepatitis C virus antigen detection were carried out. by Solid-phase enzyme immunoassay (ELISA= enzyme-linked immuno-sorbent assay)[30]. liver ultrasound was performed in each subject to assess the degree of steatosis. Liver steatosis was graded semi quantitatively on a scale of 0-3; 0: absent; 1 mild steatosis; 2, moderate steatosis; 3, severe steatosis[9, 16, 25].

Presence of liver disease was defined on the basis of abnormal liver biochemistry and/or abnormal hepatic echotexture on ultrasonography (US). Based on these finding, raised transaminases or transaminasemia, NAFLD with ultrasonographically diagnosed different grades, cirrhosis of liver (NASH related) and lastly space occupying lesion in liver (SOL) were categorized under liver disease spectrum.

Analysis of results was carried out by means of the statistical package for the social sciences (SPSS) version 20. A descriptive statistic frequency, Chi-square test, Fisher's exact test were performed to compare the variables with the disease population. P value < 0.05 was considered significant.

RESULTS

Total 123 recently diagnosed metabolic syndrome patients participated in this study. At first they were divided into three categories as per their respective ages. Group 1 i.e. between 18 - 33 years consists of 20 cases (16.3%), group 2 i.e. between 34 - 49 years consists of 36 cases (29.3%), and finally group 3 i.e. between 50 - 70 years consists of maximum number of cases i.e. 67(54.4%) cases.

Table 1 Frequency distribution of age groups

Sl No	Age group	Number of cases	Percentages (%)
1	18-33 Yrs	20	16.3
2	34-49 Yrs	36	29.3
3	50-70 Yrs	67	54.5
4	Total	123	100.0

Out of 123 cases 52.8 % were male and 47.2 % were female. Most of the study population was from non-tribal community i.e. 54.5 % ,19.5 % cases were from rural area, 35.0 % were from urban area and lastly maximum numbers of cases were from semi-urban area i.e. 45.5% In the study 15 (12.2%) patients were having BMI < 23 Kg/M^2. Whereas 45 (36.6%) patients were obese i.e. BMI > 25 Kg/M^2 and majority of the study population were over-weight i.e. BMI = 23-25 Kg/M^2.

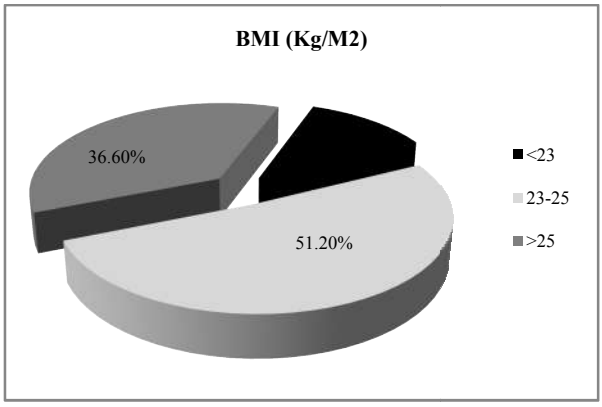

Fig 1 Pie chart of BMI in study population (n=123)

In this study, out of 123 cases majority had diabetes mellitus i.e. 74.0 % while 26.0 % were non-diabetic. Hypertension observed in 43.1% individual & 56.9% were normotensive. 95.9 % of metabolic syndrome were having raised waist circumference (WC). Dyslipidemia was present in 92.7 % cases.

Among metabolic syndrome patients, liver disease was present in 60.2% cases & was absent in 39.8 %. Out of total 60.2% cases of liver disease, 30.9% were female)and 29.3% were male and most of them [36.6%] were from 50-70 yrs old group but there was no significant co-relation observed between them with the disease prevalence (p value >0.05).

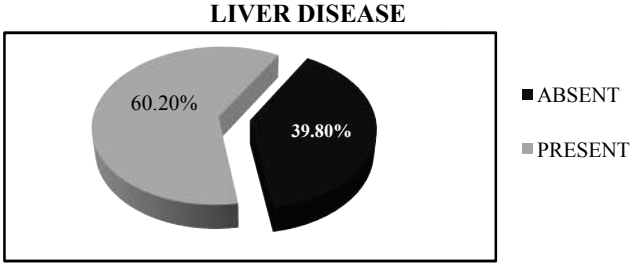

Fig 2 Pie chart showing presence of liver disease in metabolic syndrome cases (n=123).

In the study population, nonalcoholic fatty liver disease (NAFLD) was present in 34.1 % cases, nonalcoholic steatohepatitis (NASH) related cirrhosis was present in 9.8% cases and only raised transaminase level was found in 16.3 % cases. In 39.8% cases no hepatic abnormality was detected. From this study NAFLD was the most common liver disease spectrum.

Table 2 Various spectrums of hepatic abnormalities in study group (n=123).

Sl No	Spectrum	Frequency	Percent (%)
	NO Hepatic Abnormality	49	39.8
	Raised Transaminase Level	20	16.3
	NAFLD	42	34.1
	NASH related Cirrhosis	12	9.8
	Total	123	100.0

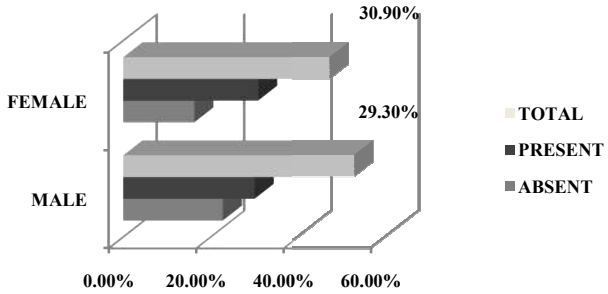

Figure 3 Histogram showing presence of liver disease among both genders

In the study majority of the liver disease patients were from non-tribal community [32.5%] and belonged to semi-urban group [26.8%)] and there was no significant co-relation observed with the prevalence of liver disease.

The study revealed that majority of the liver disease patients belonged to obese category i.e. BMI of > 25 Kg/M^2 (31.7%). There was statistically significant association observed between BMI and presence of liver disease in the study population.

58.5% cases of dyslipidemia, 73.0% cases of raised total cholesterol (TC), 85.1% cases of raised TG & lastly 81% cases of low HDL-C levels had liver disease among the study population. Almost all the components of MS were more in the disease group. None of them had significant statistical co-relation with disease prevalence except presence of dyslipidemia (p value = **0.029)**, total cholesterol (TC) level (p value = **0.001**) and low HDL-C level (p value = **0.02**), each of which had strong statistical co-relation with liver disease group (p value <0.05). There was no significant co-relation observed with raised TG level and disease prevalence.

DISCUSSION

This cross-sectional observational study was accomplished with the help of 123 randomly selected newly diagnosed metabolic syndrome patients following strict inclusion criteria & was not having any known liver diseases from before. Similar studies were also carried out using age, sex matched comparison group, samples collecting from general population, somewhere randomly selected households and also in some studies utilizing in-door patients from different departments[9, 11, 13, 15, 26].

In this study group most were male (52.8%) and mean age of the study population was 50.5 ± 13.1 (SD) years and most of them were from 50-70 yrs age group i.e. 54.5% which is

comparable to Kasapoglu B *et al* (51.3 ±3.2yrs)[11] , Prasad DS *et al* (65.5%)[29]. In the present study most of the cases were overweight (51.2%) i.e. BMI = 23-25 Kg/M^2 & 36.6% were obese i.e. BMI >25Kg/M^2 which is comparable with Kumar S *et al* (50.8%)[14], Bansal S *et al* (31%)[17].

The prevalence of overall liver diseases were 60.2%, which is showing a very high trend here. In some studies NAFLD prevalence was reported as high as 61.5% by Oh HJ *et al*[13] which is much higher than the present study. On the other hand studies like Amarapurkar D *et al* (16.6%)[8], Das TP *et al* (4.5%)[26] & Agrawal PK *et al* (18.78%)[18] had reported a bit lower prevalence of NAFLD than the present study.

Literatures had reported that the prevalence of NASH related cirrhosis in NAFLD patients is much higher than that of general population and that too in those with morbid obesity[4, 10, 16, 21]. In this study a significant proportion had asymptomatic transaminasemia or raised transaminases (16.3%) and ultrasonography had failed to detect any liver abnormality in them. This finding is very significant.
Overall the prevalence of liver disease in the present study was higher in oldest age group (50-70 yrs) comprising of 36.6% (45/74) showing synchrony with other reported studies [8, 10, 17].

Though in most of the literatures from various parts of India & over-seas had reported male preponderances [8-10, 13, 18, 21], a bit higher female preponderance was observed in disease group here (30.9% vs. 29.3%). Das TP *et al*[26] & Rawat VS *et al*[27] had reported similar gender observations. There is statistically significant association between BMI and presence of liver disease in the study group ($p < 0.05$). Presence of dyslipidemia, raised total cholesterol (TC) and low HDL-C were having significant statistical co-relation with liver disease prevalence ($p < 0.05$). Duseja A *et al*[10] had observed that raised total cholesterol, raised TG & raised HDL-C were having strong co-relation with NAFLD.

In this study we have not observed any cases of unknown hepatocellular carcinoma (HCC) by the diagnostic tool used here.

No statistically significant co-relation was found with age group, gender, community, residence, cases with raised WC, and cases with DM & HTN with presence of liver disease in the current study.

CONCLUSION

This study has revealed some interesting facts about liver disease occurrence in the North East part of India and its various clinic biochemical associations

A very high prevalence i.e. 60.2% of liver diseases namely transaminasemia or raised transaminase level, NAFLD & NASH related cirrhosis had been observed in this current study. NAFLD was the most commonly observed liver disease spectrum among the study group (34.1%). Studies across the various parts of India had shown mixed results. The proportion of transaminasemia or raised transaminases & NASH related cirrhosis were marginally higher in this r study compared to studies done in other parts of India.

Females were having a bit higher prevalence of liver diseases than males in this study, which is absent in most of the other studies. Almost all the components of MS were more in the disease group than the non-disease group.

Statistically significant co-relation observed between liver disease and the following factors like BMI, dyslipidemia, raised TC, low HDL-C levels in the study population. Though literatures had reported strong associations between raised TG, DM, raised WC with the presence of liver disease among MS patients, in this study no such co-relations were noted.

Since it was a cross-sectional study, this result needs to be validated by further long-term prospective studies.

Big numbers of studies are available across various parts of India but no previous studies are available from the present study population. The study will be considered as a foundation stone for further studies which can be conducted over long period of time, which could yield some new finding,

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