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ORIGINAL RESEARCH

Profile of alcoholic liver disease in eastern Indian population – A prospective study

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ABSTRACT

Introduction: Alcoholic liver disease (ALD) is a life-threatening disorder which has deadly consequences over uncontrolled alcohol consumption. Excessive alcohol ingestion is the forefront cause of death in people aged 15-49 years. Alcohol is the most common cause of liver cirrhosis in many countries in the world.[1] Alcohol induced toxicity is the 3rd cause of morbidity. The liver is the largest and the most complex organ in the body since it runs multiple functions in the body which includes secretion of proteins and enzymes, purification of toxins, anabolic and catabolic functions and regulation of cholesterol. It is primarily involved in the metabolism of alcohol and hence it is the most susceptible organ that undergoes alcohol related injuries. Alcohol acts as a behavioural stimulant at lower blood levels but at its higher level it acts as a central nervous system depressant damaging the cerebellum badly which alters the gait of a person.

Materials and Methods: After obtaining the clearance from the institutional ethical committee, this prospective and observational study was conducted for a period of one year from July 2016 - June 2017 in the Department, of Cardiology, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna, Bihar (India). The hospital provides primary and specialized health care facilities to people in and around certain selected districts. The patients admitted in the cardiology ward was screened according to inclusion and exclusion criteria and 150 patients were finally chosen for the study after fulfilling the selection criteria. Inclusion criteria include all patients admitted to the wide-ranging medicine ward, patients of each sex (age 18-70 years), In-Patients only, patients with alcoholic liver disease. The data collected from each patient has been documented in patient data collection form and analysed.

Multiple responses were recorded in percentages, and the data was expressed in simple mathe matics. A Microsoft Excel spreadsheet was used to create the graphs and tables.The graphs an d tables were created with a Microsoft Excel spread sheet.

Results: A total of 150 patients were included in the study in which all turned out to be a male. Most patients admitted in the medicine department were from age group 41 – 50 years followed by 25.4% in the age group of 30 – 40 years and 16.9% in the age group of 51 – 60 years respectively. Out of 150 patients 43.8% patients were suffered from Fatty Liver disease while 23.1% were suffered from Alcoholic Hepatitis and 33.1% were suffered from Cirrhosis of Liver. The secondary developments to ALD were portal HTN (13.8%) followed by Ascities (10.8%). Out of 150 patients 57.7% patients had Mild duration of hospital stay and 24.6% patients had Moderate duration of hospital stay. It was found that out of 130 patients

52.3% patients had alcohol as major risk factor while 47.7% patients had alcohol and smoking risk factor.

The resultsreveal that 67.7% of the total patients had consumed alcohol other than brandy or whiskey.

It was found that out of 130 patients 61.5% patients had alcohol periodically while 38.5% patients had alcohol daily. According to CAGE it was found that out of total 130 patients 58.5% patients had significant while 41.5% patients had non-significant. The results showed that out of total patient's 67.7% patients had other type of alcohol than brandy or whisky (Table – 5,6). It was found that out of 130 patients 61.5% patients had alcohol periodically while 38.5% patients had alcohol daily (Table – 7). According to CAGE it was found that out of total 130 patients 58.5% patients had significant while 41.5% patients had non-significant. Out of total 150 patients 69.2% patients had prescribed up to 7 medications while 30.8% patients had prescribed up to 15 medications (Table – 8,10). It shows that Vit B1, B2, B12, K was prescribed for treatment to 61.5%% patients followed by pantoprazole (53.8%), Spironolactone (42.3%) and cefotaxime (37.7%). Ceftriaxone, Propranolol, Thiamine, L-ornithine- L-asparate, were other major drugs which were prescribed to more than 30% patients.

Discussion: In the present study did not get any single female patient of ALD, this may be due girls/females are still following their Indian traditional culture that too especially in non-metro cities. In the present study, maximum number of patients was 60(42.6%) of ALD with the age group of 41-50, followed by the patients 30-40 is 33(25.4). People in this age group are more likely to be affected by excessive alcohol intake because A LD takes years to manifest its progressive nature and lethal consequences.

Conclusion: In this study, vitamins B1, B2, B12, and Vitamin K, as well as pantoprozole, Spironolactone, vitamins, cefotaxime, ceftriaxone, Thiamine, L-ornithine-L-asparate, and others, were found to be the most widely used drugs in ALD patients. The present study concludes that alcoholism is the main culprit in the development of ALD and alcohol abuse.

Keywords: Alcohol liver disease, Quality of life, Recommended drug therapy

INTRODUCTION

Alcoholic liver disease (ALD) is a life-threatening disorder which has deadly consequences over uncontrolled alcohol consumption. Excessive alcohol ingestion is the forefront cause of death in people aged 15-49 years. Alcohol is the most common cause of liver cirrhosis in many countries in the world.[1] Alcohol induced toxicity is the 3rd cause of morbidity.[2] The liver is the largest and the most complex organ in the body since it runs multiple functions in the body which include, secretion of proteins and enzymes, purification of toxins, anabolic and catabolic functions and regulation of cholesterol. It is primarily involved in the metabolism of alcohol and hence it is the most susceptible organ that undergoes alcohol related injuries.[3] Alcohol is used by mankind since ancient times for various purposes like stimulation of central nervous system and as an aphrodisiac.

Alcohol has been described as "Somaras" in Hindu mythology.[4] at lower blood levels, alcoho l functions as a behavioural stimulant, but at higher blood levels, it acts as a central nervous s ystem depressant, damaging the cerebellum and altering a person's gait. The Royal College of Physicians (RCP) recommends a weekly alcohol limit of 21 units (210g) for males and 14 un its (140g) for women. The liver and body usually manage with alcohol when drinking of small amount (1-2 units) or within prescribed limit which may help to prevent heart disease and stroke.[5] ALD comprises of three main types: Fatty liver, liver cirrhosis and Alcoholic hepatitis.[6] Alcohol metabolism provides the root for understanding alcohol-induced liver damage. Alcohol is always metabolized in the liver and Alcohol dehydrogenase (ADH) is the

major enzyme responsible in the metabolism of alcohol. Through a biochemical process known as oxidation, this enzyme turns alcohol to acetaldehyde. Acetaldehyde is toxic to the human body, even in low amounts. The enzyme aldehyde dehydrogenase (ALDH) normally converts acetaldehyde to acetate rapidly. The majority of the acetate in the bloodstream flows to other areas of the body, where it can reenter former metabolic cycles that produce energy or useful chemicals.Alcohol abuse not only affects the liver but it also affects other organs and systems such as, gastrointestinal tract, pancreas, circulatory organs, cranial nerves and blood circulation.[7]Cirrhosis complications cause a high rate of morbidity and mortality, making it a major cause of global health burden. According to the Global Burden of Disease 2010 study, cirrhosis of the liver was the cause of 1.2 percent of global Disability-Adjusted Life Years and 2% of all deaths in 2010.[8,9] Since 1980, there has been a gradual increase in cirrhosis-related mortality in India as the prevalence of cirrhosis risk factors, such as alcohol consumption, HBV, HCV, and diabetes (a key risk factor for NAFLD), has also increased.[10] In 2010, deaths from liver cirrhosis accounted for nearly one fifth (18.3%) of all liver cirrhosis deaths globally.[11]As a result, universal and consistent efforts are required to control the cirrhosis risk factors that can be avoided. Cirrhosis risk factors vary among different geographical groups around the world. Alcohol and HCV infection are the leading causes of chronic liver disease in developed countries, while alcohol and HBV infection are the leading causes in poor countries. D'Amico et al.[12] conducted a systematic review that included 118 studies (23,797 patients) and found that alcohol was the most common cause of cirrhosis (46%), followed by HCV (35%), HBV (11%), and other factors (12%). The diagnosis of ALD depends on history of alcohol ingestion, physical signs and symptoms and laboratorial investigations. Therefore, the current study was carried out for grading the alcoholic liver disease, assessment of risk factors involved and review of treatment chart for better utilization of medicaments in the management of ALD patients.

MATERIALS AND METHODOLOGY

After obtaining the clearance from the institutional ethical committee, this prospective and observational study was conducted for a period of one year from July 2016 - June 2017 in the Department of Cardiology, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna, Bihar (India).The hospital provides primary and specialized health care facilities to people in and around certain selected districts. The patients admitted in the cardiology ward was screened according to inclusion and exclusion criteria and 150 patients were finally chosen for the study after fulfilling the selection criteria. Inclusion criteria include all patients admitted to the wide-ranging medicine ward, patients of each sex (age 18-70 years), In-Patients only, patients with alcoholic liver disease. There are few exclusion criteria which include pregnant and lactating women, patients who are unconscious or in coma, unable to comply due to mental retardation, non-alcoholic liver diseases patients are excluded from the study. All the patients of either of gender diagnosed with ALD were confirmed through laboratory findings and patients who are willing to participate were included in the study. Data extracted from the case files by using data collection form by either interviewing or by extraction of data from patient's case files or both of the above were documented. The data collected from each patient has been documented in patient data collection form and analysed.

Multiple responses were recorded in percentages, and the data was expressed in simple mathematics. A Microsoft Excel spreadsheet was used to create the graphs and tables.

RESULTS

A total of 150 patients were included in the study, which all turned out to be male (Table 1). Most patients admitted to the cardiology department were from the age group of 41–50 years, followed by 25.4% in the age group of 30–40 years and 16.9% in the age group of 51–60 years, respectively. Out of 150 patients, 43.8% suffered from fatty liver disease, while 23.1% suffered from alcoholic hepatitis and 33.1% suffered from cirrhosis of the liver. The secondary developments in ALD were portal HTN (13.8%) followed by Ascities (10.8%) as shown in Table-2, whereas 10% of the patients had hepatitis. Anaemia affects a significant number of people (Table 3). Out of 150 patients, 57.7% had a mild duration of hospital stay and 24.6% had a moderate duration of hospital stay. It was discovered that out of 130 patients, 52.3% had alcohol as a major risk factor, and 47.7% had both alcohol and smoking risk factors (Table 4). The results reveal that 67.7% of the total patients had consumed alcohol other than brandy or whiskey (Table 5.5).It was discovered that 61.5% of the 130 patients consumed alcohol on a regular basis, while 38.5% consumed alcohol on a daily basis (Table 7). According to CAGE, 58.5% of the 130 patients had significant disease, while 41.5% had non-significant disease (Table 8). In a total of 150 patients, 69.2% were prescribed up to 7 medications, while 30.8% were prescribed up to 15 medications (Tables 8, 10).It reveals that 61.5% of patients were prescribed Vit B1, B2, B12, and K for treatment, followed by pantoprazole (53.8%), spironidole (42.3%), and cefotaxime (37.7%).Ceftriaxone, propranolol, thiamine, and L-ornithine-L-asparate were other major drugs which were prescribed to more than 30% of patients. All of the patients were counselled on their individual conditions for ALD consequences, and they were all encouraged to quit drinking and smoking. Patients were educated on the importance of nutritional support therapy and medication adherence.The role of nutritional support therapy and medication adherence were addressed to the patients. For the professionals, it was recommended that the significance of NLEM and its importance in patient care be explained.

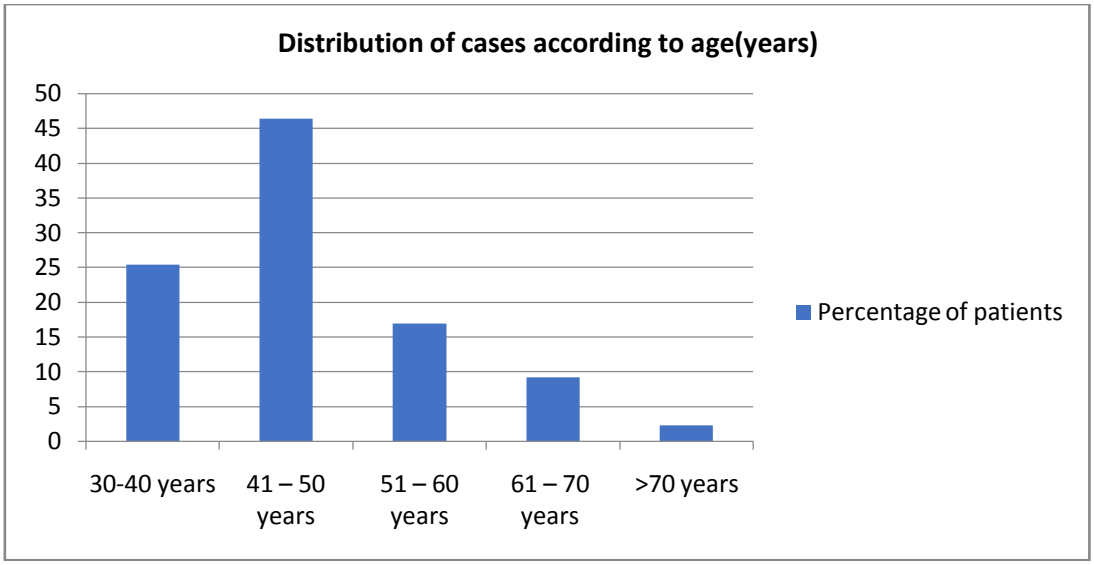
DISCUSSION

The percentage of male patients suffering from ALD was found to be 100% as all admitted patients were male, which is non-comparable to the study conducted by Vinayak S. Jamdade[13] where the male (96.7%) patients were suffering more with ALD when compared to female. In the present study did not get any single female patient of ALD, this may be due girls/females are still following their Indian traditional culture that too especially in non-metro cities. In the present study, maximum number of patients were 60(42.6%) of ALD with the age group of 41-50, followed by the patients 30-40 is 33(25.4) which is related to the study conducted by Vinayak S. Jamdade [13] which showed that the patients (34.74%) with the age group of 31-40 years were mainly affected.

People in this age group are more likely to be affected by excessive alcohol intake because A LD takes years to manifest its progressive nature and lethal consequences (Table no. 01).

Table 1: Distribution of Cases According to Age

Age (Years)	No. of Patients	Percentage (%)
30 – 40	38	25.4
41 – 50	70	46.4
51 – 60	25	16.9
61 – 70	14	9.33
>70	3	2.3
Total	150	100



Graph 1: Distribution of Cases According to Age (in years)

In the present study it is analysed that greater number of patients affected with Fatty liver were 57 (43.8%) and followed by Liver cirrhosis 40 (33.1%). Patients were predominantly high with Fatty Liver as it is first stage of the ALD and upon immediate starts of treatment disease did not progress. (Table no.02)

Table – 2: Distribution of Cases According to Types of Alcoholic Liver Disease

Types of Alcoholic Liver Disease	No. of patients	Percentage
Alcoholic hepatitis	35	23.1
Cirrhosis of Liver	50	33.1
Fatty liver	65	43.8
Total	150	100

The secondary developments to ALD seen were portal hypertension (13.8%), Ascities (10.8%), hepatitis (10%) and anemia (6%) in most of patients. Abstinence improves the survival and prognosis of patients with ALD and prevents progression to liver cirrhosis through histologic development and decline in portal pressure. (Table no.03).

Table – 3: Distribution of Cases According to Types of Alcoholic Liver Disease

Secondary Developments	No. of Patients	Percentage %
Portal Hypertension	21	13.8
Ascites	16	10.8
Hepatitis	15	10
Anemia	7	4.6
Diabetes	7	4.6
Chronic liver disease	5	3.1
Psychotic syndrome	5	3.1
Hepatic coma	3	2.3
Jaundice	3	2.3

Based on the length of hospital stay during the treatment period; it was observed that 57.7% of patients stayed for about 1-7 days. The patients who are admitted to the hospital at their initial stage of ALD did not lead to further severity of the disease as they have been started treatment (Table no.04)

Table 4: Distribution of Cases According to Duration of Hospital Stay

Duration of hospital stay	No. of patients	Percentage (%)
Mild (1 – 7 days)	86	57.7
Moderate (8 – 15 days)	37	24.6
Rigorous (16 – 30 days)	27	17.7
Total	150	100

Alcohol was a major risk factor in 52.3% patients, followed by alcohol and smoking in 47.7%. Alcohol is well known to cause liver disorders because of the fact that healthy liver tissues are replaced with scar tissues that ultimately leads to improper functioning of liver. (Table no.05).

Table 5: Distribution of Cases According to Risk Factors

Risk factors	No. of patients	Percentage (%)
Alcohol	78	52.3
Alcohol & smoking	72	47.7
Total	150	100

With 150 patients 67.7% patients had other type of alcohol (local brands) which was predominantly high followed by brandy and whisky. Local brands of alcohol are more preferred in rural areas due to economic factor. (Table no.06).

Table 6: Distribution of Cases According to Types of Alcohol

Types of Alcohol	No. of patients	Percentage (%)
Brandy	30	20
Whisky	18	12.3
Others (Local brands)	102	61.5
Total	150	100

It was observed from the total of 150 patients, 61.5% patients had alcohol periodically while 38.5% patients had alcohol daily may be due to addiction of alcohol consumption (Table no.07).

Table 7: Distribution of Cases According to Frequency

Frequency	No. of patients	Percentage (%)
Daily	58	38.5
Periodically	92	61.5
Total	150	100

69.2% patients had prescribed up to 7 medications while 30.8% patients had prescribed up to 15 medications. These medications are prescribed based on their individual health conditions of the patient (Table no.08).

Table 8: Distribution of cases according to number of medications

No. of medications	No. of patients	Percentage (%)
Upto 7	104	69.2
Upto15	46	30.8
Total	150	100

A CAGE questionnaire is the method to assess the clinical significance of alcohol addiction which is directly or indirectly involved in fast progression of ALD. According to CAGE questionnaire out of 130 patients, 58.5% of patients were clinically significant followed by 41.5% patients were non-significant which is contradictory to the study conducted by

Mohannad Dugum [14]which shows non-significant patients were high when compared to significant (Table no.09).

Table 9: Distribution of Cases According to CAGE Questionnaire.

CAGE	No. of patients	Percentage (%)
Significant (2 or >2)	88	58.5
Non – significant (0 or 1))	62	41.5
Total	150	100

L-Ornithine- L -aspertate, Ursodiol, and other medications are commonly used to treat alcoholic liver disease.In this study, the percentage of L-Ornithine-L Aspartate was 32.3%, followed by Ursodiol (18.5%). Patients were administered Vitamin supplements 61.5 percent of the time and Pantoprazole 53.8 percent of the time, according to the prescribi ng pattern. This clearly demonstrated that in ALD patients, vitamins, proton pump inhibitors, hepatoprotective medications, and laxatives are commonly prescribed. The most common app lication of vitamin supplements in patients could be to speed up the recovery of liver function s. Second, Pantoprazole may have been administered due to a gastrointestinal issue linked to ALD. This is connected to Vinayak S Jamdade's [13] study, in which pantoprazole (78.67%) wa s the most commonly recommended drug (Table no.10).

Table 10: Distribution of Cases According to Generic Name of Drugs Prescribed As Per NLEM.

Generic name prescribed	No. of patients	Percentage (%)
Vitamin B1, B2, B12, K	92	61.5
Pantoprazole	81	53.8
Spironolactone	63	42.3
Cefotaxime	57	37.7
Ceftriaxone	57	37.7
Propranolol	55	36.9
Thiamine	52	34.6
L – ornithine L - aspartate	48	32.3
Furosemide	38	25.4
Ondansetron	38	25.4
Ofloxacin	35	23.1
Folic acid	35	23.1
Ursodiol	28	18.5
Vitamin A	23	15.4
Metadoxime	17	11.5
Lorazepam	15	10
Albumin	15	10
Tramadol	14	9.8
Sucralfate	13	8.5
Lactulose	4	3.1
Phenytoin	3	2.3
Hydrocortisone	2	1.5

A recent study including 175 alcoholic cirrhotic patients, 140 non-alcoholic cirrhotic patients, 255 non-alcoholic controls, and 140 alcoholic controls, done in Lucknow, revealed that the ADH1C*1/*1 genotype exhibited a significant association with alcoholic liver cirrhosis while ADH1B genotypes did not show any significant association.[16]

Another study done at AIIMS including 174 alcoholics showed that hepatic transaminases were significantly increased, age of onset of alcohol dependence was significantly lower and duration of dependence was significantly higher in those with ALDH2*1/*1 as compared to the ALDH2*2/*2 genotype, suggesting a protective role of the latter genotype from alcoholism as well as alcoholic liver disease.[17]

Another study done by Bhaskar et al in 397 healthy individuals from six tribal populations from various parts of India reported that the ALDH2*2/*2 allele was absent in Indians.[18]

Patient related recommendations - Stop alcohol intake immediately, stop smoking, Adherence to medication, Nutritional intake on regular basis, Patient counselling for ALD consequences

Physician related recommendations - Use of corticosteroids on conditional basis, Nutritional support, therapy, Use of baclofen on conditional basis, Prescribe the drug from NLEM on required basis.

Table 11: Recommendations for ALD.

Patient related recommendations
1. Stop alcohol intake immediately
2. Stop smoking
3. Adherence to medication
4. Nutritional intake on regular basis
5. Patient counselling for ALD consequences
Physician related recommendations
1. Use of corticosteroids on conditional basis.
2. Nutritional support therapy.
3. Use of Baclofen on conditional basis.
4. Prescribe the drug from NLEM on required basis.

CONCLUSION

According to NLEM, Hepamerz, ursodiol is the most commonly prescribed liver protective's, followed by Liveril excluding from NLEM but are widely prescribed in our hospital.

In this study, vitamins B1, B2, B12, and Vitamin K, as well as pantoprozole, Spironolactone, vitamins, cefotaxime, ceftriaxone, Thiamine, L-ornithine-L-asparate, and others, were found to be the most widely used drugs in ALD patients. The values of prescribing indicators for average number of drugs per encounter, generic drug, injections, and drugs from NELM shows, deviation from the standard prescribing guidelines values recommended by World Health Organisation. Therefore, many multi-centred studies are required to be conducted which helps us to arrive at a conclusion to draw the best results on prescribing pattern of alcoholic liver disease in India. Therefore, these factors should be monitored very closely in order to ensure proper prescribing habits in the Indian hospitals. Random prescribing habits often leads to ineffective and unsafe treatment, increases the treatment cost, greater chances of adverse consequences and drug interactions and finally causes distress and harmful to the patients.[7] So, it is necessary to promote the rational drug use in developing countries with the help of WHO drug use indicators.[15] S Liveril (Silymarin) drug is a liver protective used extensively in the present study and proven its efficacy for ALD treatment, hence it may be recommended to include in the NLEM list for the better patient outcome. The present study concludes that alcoholism is the main culprit in the development of ALD and alcohol abuse.

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