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ASSESSMENT OF CLINICAL PROFILE AND TREATMENT CHART REVIEW FOR ALCOHOLIC LIVER DISEASE (ALD) PATIENTS: A PROSPECTIVE AND OBSERVATIONAL STUDY

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ABSTRACT

Background/Aim: Alcohol remains one of most common cause of liver disease in India, hence the present study was undertaken to assess the clinical profile and treatment chart review of alcoholic liver disease (ALD) patients.

Materials and Methods: Hospital based prospective and observational study was carried out for a period of nine months in a tertiary care hospital of south India**.** All the patients of either gender diagnosed with ALD were enrolled in the study and patient consent was taken, the data related to the patients of ALD were documented in a structured patient data collection form and analyzed carefully.

Results: ALD was mainly affected in male with age group of 41-50 years. Out of 130 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 hypertension (13.8%) followed by Ascities (10.8%) and Hepatitis (10%). The major risk factors involved in ALD was alcohol *per se* (52.3%) and, alcohol and smoking exaggerate the disease condition. The Periodic (61.5%) and regular basis (38.5%) of alcoholism for chronic period of time may land up with ALD. Polypharmacy is essential for the treatment of ALD as it involved multiple secondary developments to ALD. The patients were intervened and counselled on their individual basis for ALD consequences, and motivated for cessation of alcohol and smoking.

Conclusion: The study enlightens that the early diagnosis and its beneficial outcomes that can exponentially curtail the mortality rate of ALD. Similarly the optimal drug therapy regimen and patient counseling may improve the patient's quality of life.

Keywords: Alcoholic Liver Disease; Optimal Drug Therapy; Patient Counselling; Improved Quality of Life.

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INTRODUCTION

Alcoholic liver disease (ALD) is a serious disorder and has deadly consequences over excessive alcohol consumption. Excess Alcohol ingestion is the leading cause of death in people aged with 15-49 years In most of the countries, alcohol is the most common cause of liver cirrhosis [1]. Alcohol induced toxicity is the 3rd cause of morbidity [2].

The liver is a largest and most complex organ of the body; it performs multiple functions in the body it may include, secretion of proteins and enzymes, purification of toxins, anabolic and catabolic functions and cholesterol regulation. It is primarily involved in the metabolism of alcohol and most susceptible for alcohol related injuries [3].

Alcohol is used by mankind since ancient times for various purposes; it includes stimulation of central nervous system and as an aphrodisiac. According to Hindu mythology, alcohol has been stated as "Somaras" [4]. Alcohol acts as a behavioural stimulant at lower blood levels but at its higher level it acts as a central nervous system depressant. Royal college of physicians (RCP) advice a weekly limit of alcohol ingestion, for men it is 21 units (210g) and 14 units for women. The liver and body usually cope with drinking of small amount (1-2 units) or within prescribed limit 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 origin for understanding alcohol-induced liver damage. Alcohol is metabolized in the liver and Alcohol dehydrogenase (ADH) is the major enzyme concerned in the metabolism of alcohol. This enzyme converts alcohol to acetaldehyde through a chemical process called oxidation. Even in low concentrations, Acetaldehyde is vastly toxic to the body. Normally however, the enzyme aldehyde dehydrogenase (ALDH) rapidly oxidizes acetaldehyde to acetate. Most of the acetate travels throughout the bloodstream to other parts of the body, where it can enter former metabolic cycles that construct energy or useful molecules. According to WHO, alcohol ingestion ranks world third largest burden disease. Alcohol abuse not only affects the liver, it also affects other organs and systems such as, gastrointestinal tract, pancreas, circulatory organs, cranial nerves and blood circulation[7]. The diagnosis of ALD is depends on history of alcohol ingestion, physical signs and symptoms, and laboratorial investigations. Hence the present study was undertaken for grading of 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 METHODS

Study design and settings: A prospective and observational study was conducted for a period of nine months in a tertiary care hospital of Shri B.M.Patil medical college hospital and Research centre, in Vijaypur, after obtaining the Institutional ethical Committee Clearance. The hospital provides primary and specialized health care facilities to people in and around Vijayapur district. The patients admitted to medicine ward was screened according to inclusion and exclusion criteria and 130 patients were finally selected for the study.

Inclusion criteria:

- ✓ All the patients admitted to the wide-ranging medicine ward.
- ✓ Patients of each sex, of age 18-70 years.
- ✓ In-Patients only
- ✓ Patients with alcoholic liver disease are included.

Exclusion criteria:

- ✓ 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

Source of data: Data extracted from the case files by using data collection form (includes demographic data, chief complaints, social history, side effects, past medical history and past medication history, laboratory details, diagnosis and treatment chart).

Study procedure: All the patients of either of gender diagnosed with ALD by confirmed laboratory findings and patients 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. The data collected from each patient has been documented in patient data collection form and analyzed.

Sample size:

The sample size was calculated by the following formula with help of statistician.

$$N = (Z\,\alpha^2 \times S^2) / d^2$$

Where n= Sample size

Z= Level of significance

d^2 = 10% absolute error

S^2= Variance of a sample

$\alpha^{2\,=}$ Probability of type 1 error

Statistical analysis: The data were expressed in simple mathematics and multiple responses were reported in terms of percentages. The graphs and tables were generated using the Microsoft excel sheet.

RESULTS

A total of 130 patients were included in the study, out of them all were males (Table 1). Maximum patients admitted to medicine department (46.2%) were from age group 41-50 years followed by 25.4% from age group 30-40 years and 16.9% from age group 51-60 years.

Table 1: Distribution of Cases According to Age:

AGE (YRS)	No. of patients	Percent%
30-40	33	25.4
41-50	60	46.2
51-60	22	16.9
61-70	12	9.2
>70	3	2.3
Total	130	100

Out of 130 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%) whereas, 10% patients had Hepatitis. A significant number of patients also had Anaemia.

Out of 130 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 results showed that out of total patient's 67.7% patients had other type of alcohol than brandy or whisky. 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. Out of total 130 patients 69.2% patients had prescribed up to 7 medications while 30.8% patients had prescribed up to 15medications. 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. All the patients were intervened and counselled on their individual conditions for ALD consequences and motivated for cessation of alcohol and smoking. 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.

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 [8] 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 follows 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 [8] which showed that the patients (34.74%) with the age group of 31-40 years were mainly affected. These age group people are more likely to be affected due to excessive alcohol consumption as ALD requires years together to show its progressiveness and lethal consequences. (Table no. 01).

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

Types of Alcoholic Liver Disease	No. of patients	Percent %
Alcoholic Hepatitis	30	23.1
Cirrhosis of Liver	43	33.1
Fatty Liver	57	43.8
Total	130	100

In the present study it is analysed that more 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 progressed (Table no.02).

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: Secondary Developments to ALD.

Secondary Developments	No. of patients	Percent %
Portal HTN	18	13.8
Ascities	14	10.8
Hepatitis	13	10.0
Anemia	6	4.6
Diabetes (Comorbid)	6	4.6
Chronic liver disease	4	3.1
Psychotic syndrome	4	3.1
Hepatic coma	3	2.3
Jaundice	3	2.3
Alcohol withdrawal symptom	3	2.3
Hepatic precoma	3	2.3
Acute Gastritis	2	1.5

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	Percent%
Mild(1-7 days)	75	57.7
Moderate(8-15 days)	32	24.6
Rigorous(16-30 days)	23	17.7
Total	130	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	Percent%
Alcohol	68	52.3
Alcohol & Smoking	62	47.7
Total	130	100

With 130 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	Percent%
BRANDY	26	20
WHISKY	16	12.3
OTHERS (Local Brands)	88	67.7
Total	130	100

It was found that out of 130 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	Percent%
Daily	50	38.5
Periodically	80	61.5
Total	130	100

Table 8: Distribution of cases according to number of medications

No. of Medications	No. of patients	Percent%
Up to 7	90	69.2
Up to 15	40	30.8
Total	130	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).

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 Clinical significant followed by 41.5% patients were non-significant which is contradictory to the study conducted by Mohannad Dugum [9] 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	Percent%
Significant(2 or > 2)	76	58.5
Non-Significant(0 or 1)	54	41.5
Total	130	100

The primary drugs used for the alcoholic liver diseases are L-Ornithine-L-Aspertate, Ursodiol etc. The percentage of L-Ornithine-L-Aspartate in the present study was (32.3%) followed by Ursodiol (18.5%). Prescribing pattern of drugs indicates 61.5% patients prescribed with Vitamin supplements and 53.8% patients prescribed with Pantoprazole. This clearly indicated that there is a tendency to prescribe vitamins, proton pump inhibitors, hepatoprotective agents and laxatives in ALD patients. The possible reason behind most frequent use of vitamin supplements in patients may be for quick recovery of liver functions. Secondly Pantoprazole was prescribed may be due to gastric disorder associated with ALD. This is related to the study conducted by Vinayak S Jamdade [8] where the pantoprazole (78.67%) was predominantly prescribed (Table no.10).

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

Sr.no	Generic name Prescribed	NLEM (Yes/No)	No.of Patients	Percentage%
1	Vitamin B1 ,B2,B12, K	Yes	80	61.5
2	Pantoprazole	Yes	70	53.8
3	Spironolactone	Yes	55	42.3
4	Cefotaxime	Yes	49	37.7
5	Ceftriaxone	Yes	49	37.7
6	Propranolol	Yes	48	36.9
7	Thiamine	Yes	45	34.6
8	L-ornithine- L-asparate	Yes	42	32.3
9	Furosemide	Yes	33	25.4
10	Ondansetron	Yes	33	25.4
11	Ofloxacin	Yes	30	23.1
12	Folic acid	Yes	30	23.1
13	Ursodiol	Yes	24	18.5
14	Vitamin A	Yes	20	15.4
15	Metadoxine	Yes	15	11.5
16	Rifaximine	Yes	13	10.0

17	Lorazepam	Yes	13	10.0
18	Albumin	Yes	13	10.0
19	Tramodol	Yes	12	9.2
20	Sucralfate	Yes	11	8.5
21	Hyoscine Butyl Bromide	Yes	11	8.5
22	Lactiol Monohydrate	Yes	9	6.9
23	Lactulose	Yes	4	3.1
24	Lactulose	Yes	4	3.1
25	Phenytoin	Yes	3	2.3
26	Hydrocortisone	Yes	2	1.5
27	Pentoxifylline	Yes	1	0.8
28	Metronidazole	Yes	1	0.8

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 was the most commonly prescribed liver protective's, followed by Liveril excluding from NLEM but are widely prescribed in our hospital. In the present study it is found that Vitamin B1, B2, B12, and Vitamin K, pantoprozole, Spironolactone, vitamins, cefotaxime, ceftriaxone, Thiamine, L-ornithine- L-asparate, etc. are the commonly used medications 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 WHO. Hence more multi-centred studies are required to be conducted to draw the best results on prescribing pattern of alcoholic liver disease in India. Therefore, these factors should be monitored extreme closely in order to ensure proper prescribing habits in the Indian hospitals.

Bad prescribing habits often leads to ineffective and unsafe treatment, increases the treatment cost, increases the chance 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 [10]. 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 plays an important role in the expansion of alcohol-related liver damages. ALD dependent secondary developments were seen in most of patients such as, portal hypertension, asciitis and anemia. Treatment regimen review of the present work indicates most of the drugs prescribed were from the NLEM list, which authenticate the rationality of drug usage in the hospital set up.

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