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Research Article

### EVALUATION OF DRUG UTILIZATION PATTERN OF PATIENTS WITH ALCOHOLIC LIVER DISEASE IN JAYANAGAR GENERAL HOSPITAL

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**Abstract:**

**Background:** Alcoholic liver disease is a serious consequences of drinking alcohol and alcohol dependence is one of the more serious public health issues in the world. It not only affects health but is also a social and economic burden. Pharmacotherapy is the main stay of treatment along with behavioural therapy for alcohol addiction. Present study was done to analyse the prescribing pattern of drugs in alcohol liver disease.

**Aims and objective:** the aim of the study is to evaluate drug utilization pattern of drugs in patients with ALD.

**Materials and Methods:** a prospective observational study was done by analysing the medical records of patients with ALD at Jayanagar general hospital for 6 months. A total of 80 case records of patients with ALD were reviewed and details such as demographic, specified drugs prescribed were recorded and analysed.

**Results:** overall 567 drugs were prescribed for 80 patients, out of which GI Drugs were the most commonly prescribed drugs (20.49%) followed by vitamins (18.91%), antibiotics (14.39%) diuretics (11.61%), hepatoprotectants (10.60%), saline (8.85%), benzodiazepines (8.08%) and less commonly anti emetics (7.07%). The most commonly prescribed antimicrobial drug was Ceftriaxone (84%), Diuretic was Furosemide (72%) and among Hepatoprotective agents Ursodeoxycholic acid (65%) were more commonly prescribed.

**Conclusion:** GI DRUGS along with vitamins and antibiotics were the most commonly prescribed drugs for patients with ALD.

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**INTRODUCTION:**

According to the world health organization (WHO), drug utilization is the process of prescription, distribution and use of drugs in a country, regarding to its outcomes, medical, social, and economic. It is a system of ongoing, systematic, criteria based on evaluation of drug use that will help ensure medicines are used appropriately. By assessing drug utilization it collects, analyses and interprets drug usage pattern to improve the quality of drug use and patient outcomes<sup>2</sup>.

The liver is the most important organ which is responsible for alcohol metabolism; it is especially prone to alcohol related injury which can alter the normal function of the liver. Alcoholic liver disease (ALD) is a major cause of chronic liver disease all over the world, that it can be started from simple steatosis to cirrhosis<sup>2</sup>. ALD and its complications are the major cause of morbidity and mortality worldwide. Approximately two million people are suffering from ALD. Alcoholism is associated with more than 60 diseases, but most mortality of alcoholism results from alcoholic liver disease (ALD). The rate of alcohol consumption in India has been increased as high as 106.7% in the last 10 years. As per WHO researches about 30% of Indians consume alcohol, out of which around 50% are hazardous drinkers and the mean age is from 28 years to 17 years unfortunately<sup>28</sup>. Generally speaking, that alcohol is responsible for 5.9% of global mortality worldwide and 2.5 million deaths per year. Men with age between 35-64 years have high risk rate. Alcohol consuming for more than 10 years (80 gram of alcohol per day) will develop liver disease at a rate of nearly 100%<sup>31</sup>.

According to ICD-10, the Alcohol Dependence Syndrome (ADS), is defined as a cluster of physiological, behavioural, and cognitive phenomena in which the use of alcohol takes on a much higher priority for a given individual than other behaviours that once had greater value. Cirrhosis is defined as the histological development of regenerative nodules surrounded by fibrous bands in response to chronic liver injury that leads to portal hypertension and end stage liver disease. Around two billion people worldwide consume alcoholic beverages regularly and over 76 million people suffer from alcohol use disorders (AUD).

There are many complications associated with alcohol abuse such as alcohol intoxication, alcohol tolerance, alcohol dependence, and alcohol withdrawal. Diseases associated with alcohol abuse can be prevented with moderate consumption and behavioural modifications should be considered. The management of patient conditions also depends upon the existing

comorbidities. This gives idea to generate our study. The laboratory findings that are frequently elevated in ALD are SGOT, SGPT, AST, Bilirubin, etc. The general clinical features include abdominal pain, nausea, vomiting, etc.

Management consists of a multi-disciplinary approach including alcohol cessation, fluid and electrolyte correction, treatment of alcohol withdrawal, and pharmacological therapy based on the severity of the disease. This study is mainly focused on drug utilization pattern in patients diagnosed with alcoholic liver disease and it is an attempt to gain insight into prescribing patterns of drugs in various complications of ALD including specific therapy.

Extent of liver damage depends on quantity, duration and pattern of drinking. Hepatitis, interaction with host factors (i.e., gut microbiota), gender, genetic, nutritional factors and comorbidities are the main factors influencing the development and the progression of ALD. Individuals who are not yet dependent or addicted to alcohol, but drinks beyond a safe level, should be targeted by health policies and health professionals.

We performed a prospective study to identify the risk, nature and treatment of ALD. The study of drug utilisation pattern seeks to monitor, evaluate and suggests required modifications in prescribing patterns so has to make the therapy rational and cost effective<sup>31</sup>

**MATERIALS AND METHODS:**

The study was carried out in Jayanagar General Hospital, Bangalore which is a 400 bedded secondary care hospital. Inclusion Criteria of the subjects were i) Any in-patient and out-patients diagnosed with alcoholic liver disease admitted to general medicine department ii) Alcoholic dependent syndrome. Exclusion Criteria of the study were, i) Pregnant and unconscious patient ii) Patients with other substance abuse along with alcohol were not studied.

**Ethical Clearance**

The study was approved by the Institutional Ethical Committee of Jayanagar General Hospital, Bangalore with approval number IEC No; NCP/IHEC-CERTI-003/2018-2019.

**METHODOLOGY:**

Data was collected using a self-designed data collection form, which contains details like demography, chief complaints, history of present illness, medication and medical history. All the

patients admitted to general medicine with alcoholic liver disease and patients visiting General Medicine OPD with alcohol dependence syndrome are included in the study. Detailed patient information was obtained from patient's case sheet, including patient demographics, diagnosis, and history of medical and medication details. The laboratory data details like blood pressure values, Liver function test, etc. were noted down. Details about the pharmacotherapy with respect to the use of drug utilization pattern of patients with alcoholic liver disease were collected.

### RESULTS:

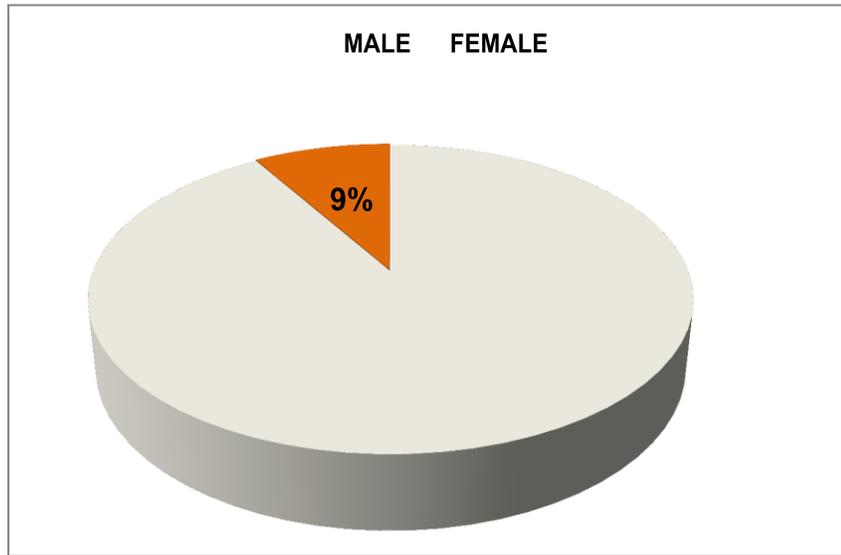
A total of 80 Alcoholic liver disease patients were admitted in the medicine department in Jayanagar

general hospital for a period of 6 months was analysed. Out of which 73 patients were male (91%) and 7 were female (9%)(Figure 1), this indicates that the burden of alcoholic liver disease(ALD) is more on the male patients. In the present study ,the majority of the female(71.43%) patients were more risk to ALD followed by male (35.64%) belonged to the age group of 31-40 years, followed by the age group 21-30 years male(26.02),female(0%),for 41-50 age group male(19.17%), female(0). less comparatively male (19.17%) female (28.57%) among patients above 50 years. The demographic profiles have been described in (Table 1).

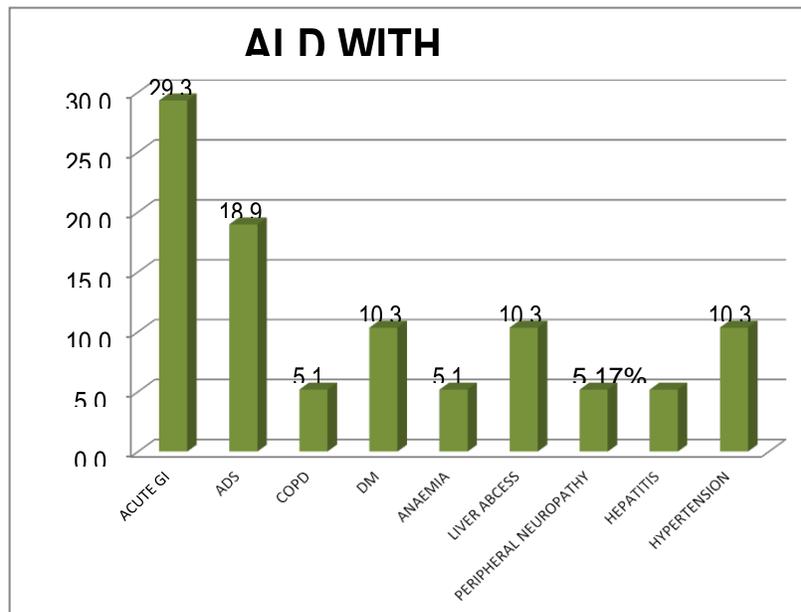
AGE (YEARS)	MALES		FEMALE		TOTAL	TOTAL
	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE
21-30	19	26.02	0	0	19	23.75
<b>31-40</b>	<b>26</b>	<b>35.64</b>	<b>5</b>	<b>71.43</b>	<b>31</b>	<b>38.75</b>
41-50	14	19.17	0	0	14	17.5
ABOVE 50	14	19.17	2	28.57	16	20
TOTAL	73	100	7	100	80	100

Laboratory evaluation of the 80 subjects reflected that Serum glutamic oxalic-acetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT),alkaline phosphatase (ALP), total bilirubin, direct bilirubin, and albumin as well as serum protein were found to be elevated in the disease. SGOT, SGPT and ALP levels were at high while albumin and protein found to be slight increase or decrease in there level. Baseline LFT are shown in (TABLE 2).

PARAMETER	MEAN	SD
albumin (g/dl)	3.93	± 1.31
serumprotein(g/dl)	6.66	± 1.62
Totalbilirubin(mg/dl)	2.38	± 1.89
Directbilirubin(mg/dl)	1.32	± 1.43
SGOT(U/l)	67.72	± 42.91
SGPT(U/l)	59.73	± 31.99
ALP(U/I)	217.1	± 90.52

**Figure 1: Gender distribution in alcoholic liver disease**

The most common comorbidity found with ALD was Acute gastritis (29.31%) followed by ADS alcohol dependent syndrome (18.97%), moderately liver abscess (10.34%). The least found complication was anaemia and peripheral neuropathy are 5.17% (Figure 2).

**Figure 2: Comorbidities associated with alcoholic liver disease**

On the whole, a total of 567 drugs were prescribed for 80 patients with ALD. The most commonly prescribed drugs were GI DRUGS (20.49%), vitamins (18.91%), and antibiotics (14.39%) followed by diuretics (11.61%), hepatoprotectants (10.60%), saline(8.85%), benzodiazepines (8.08%) and less commonly anti emetics (7.07%) (Figure 3). Among the Hepatoprotective agents ursodeoxycholic acid (65%) was the most commonly prescribed drug followed by Silymarin (14%), L-ornithine L-aspartate (14%) and LIV 52 (7%) being the least prescribed (Figure 4). GI drugs are the most commonly prescribed drugs and among them parentally and orally given pantoprazole (81%) followed by ranitidine (16%) and omeprazole(3%) (Figure 5).

Figure 3: Prescription pattern of drugs in ALD

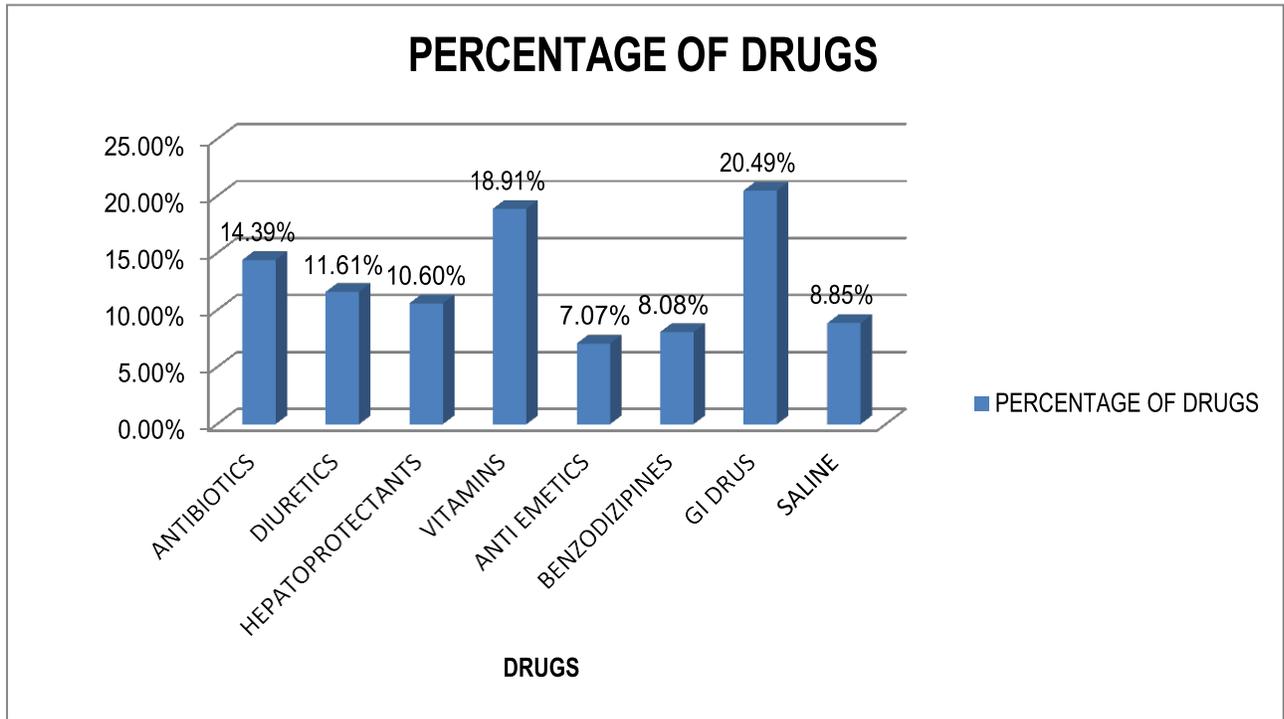
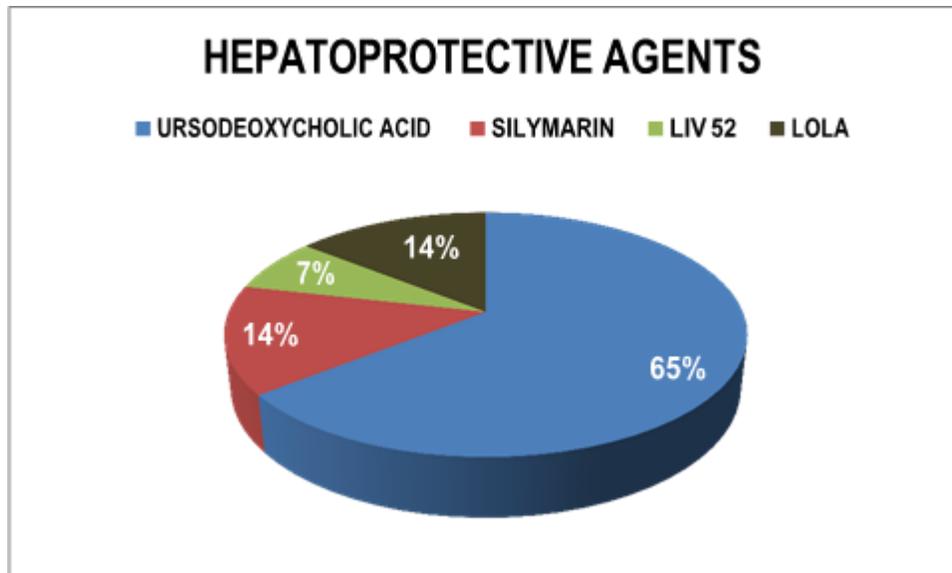
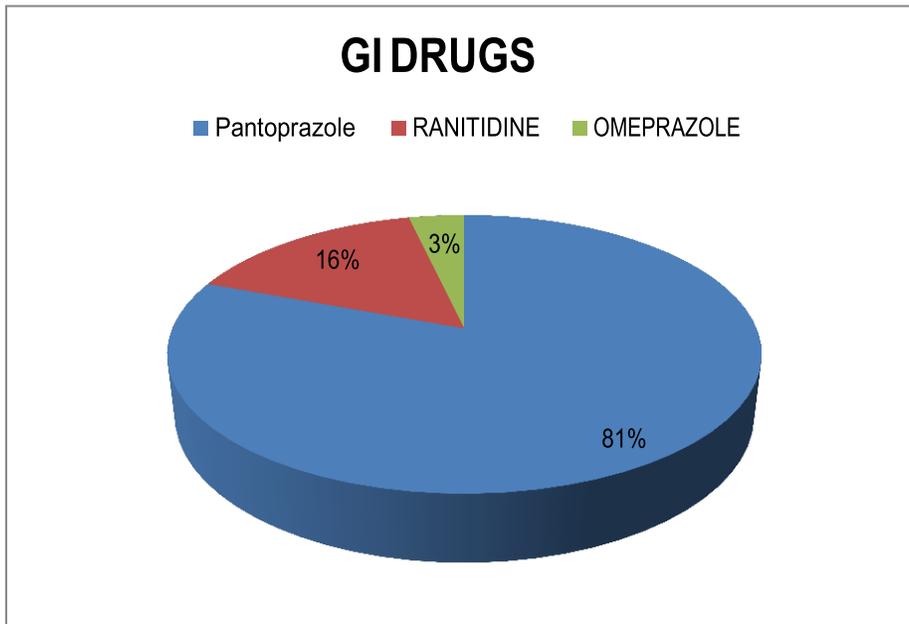


Figure 4: Prescription pattern of Hepatoprotective agents in patients with alcoholic liver disease

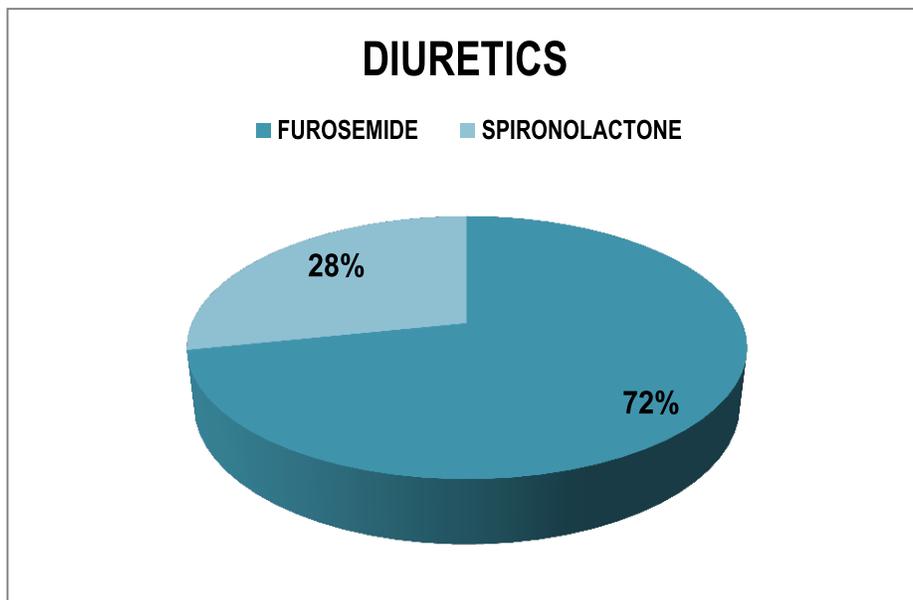


**Figure 5:** Prescription pattern of Anti Gastric drugs in patients with alcoholic liver disease

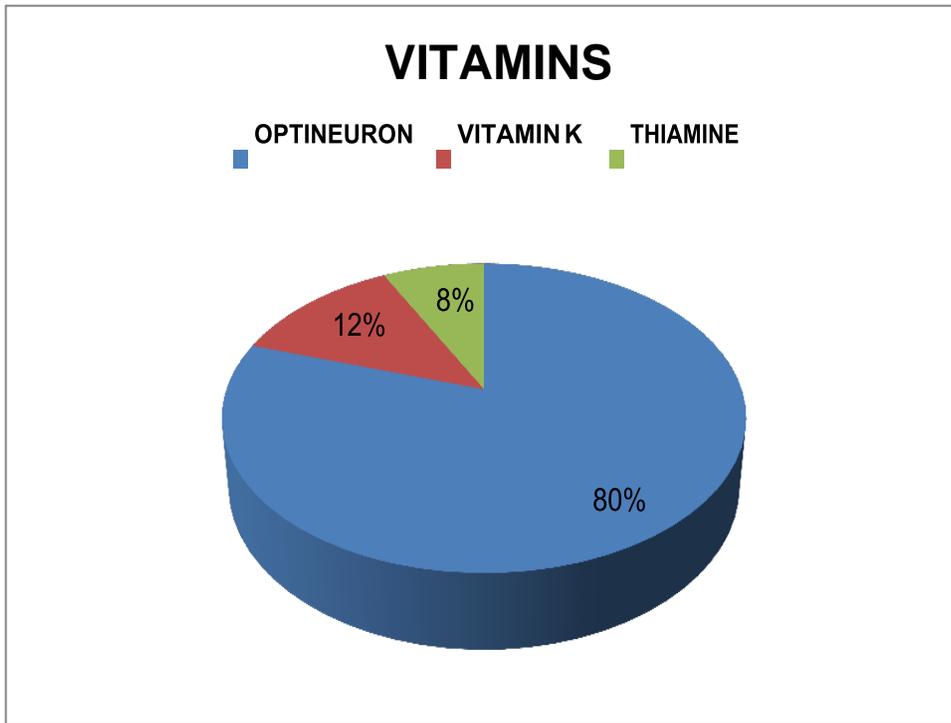


Among diuretics, the most commonly prescribed drugs was furosemide (72%), followed by spironolactone (28%) (Figure 6). Whereas In vitamins, which were the second most common category of drugs prescribed, parenteral optineuron (80%) was most prescribed and least were vitamin k (12%) and thiamine (8%) (Figure 7). Out of antimicrobials drugs, ceftriaxone were highest prescribed drugs (84%) followed by metronidazole (16%) (Figure 8).

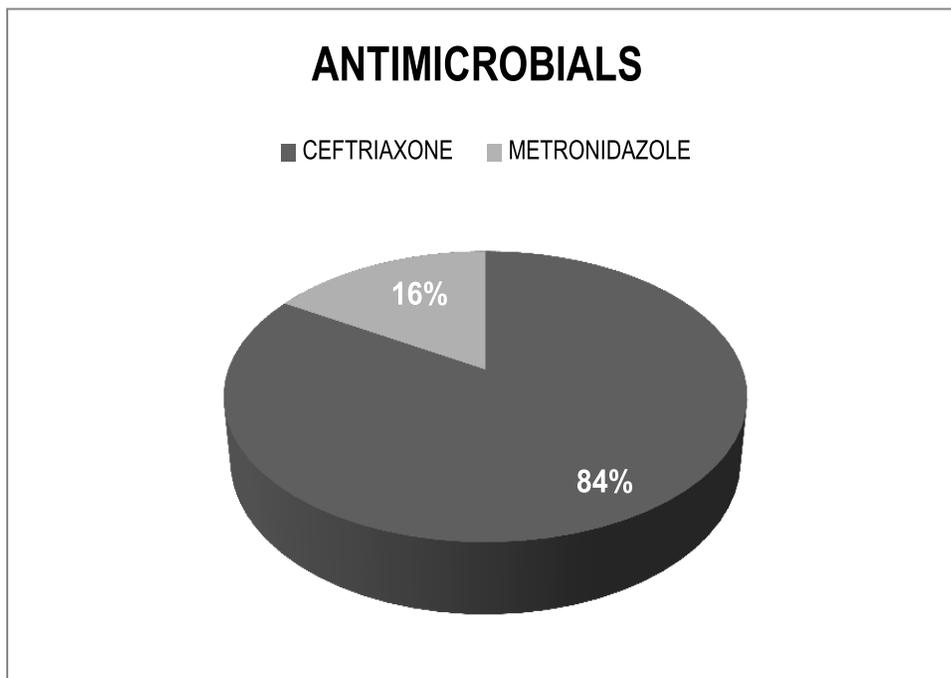
**Figure 6:** Prescription pattern of Diuretics in patients with alcoholic liver disease



**Figure 7:** Prescription pattern of Vitamins in patients with alcoholic liver disease



**Figure 8:** Prescription pattern of Antimicrobials agents in patient with alcoholic liver disease



**DISCUSSION:**

In the total 80 cases of ALD taken, the majority of patient who belong to the age group 31-40years(38.75%), followed by age group 21-30years(23.75%), above 50(20%), 41-50(17.5%). VINAYAK S et al conducted a similar study reveals that more patient in the age group of 31-40years followed by 41-50years, 18-30years, 51-60years, 61-70years, as per the study made by VIJAYAN M et al the majority of patient belong to age group 51-60years followed by 41-50years, 21-30years, 71-80years. A study by HUNG D H et al showed males more risk to ALD followed by females and in similar a prospective study showed 91% males and 9% female.

In our study GI drugs(20.49%) were the most commonly prescribed to all patients with alcohol liver disease next to it frequently prescribed drugs include vitamins(18.93%), antibiotics(14.39%), diuretics(11.6%), hepato-protectants(10.6%), salines(8.83%), benzodiazepines (8.08%) and antiemetics (7.07%) as per patient disease comorbidities. In a study done by VINAYAK S et al explained GI drugs were most commonly prescribed drug followed by vitamins, hepatoprotectives, antibiotics, diuretics, benzodiazepines, as per study made by KOLASANI B P et al hepatoprotective drugs were most commonly prescribed drug followed by antibiotics, GI dugs, Vitamins, IV fluids, anti-emetics, diuretics and corticosteroids.

As mentioned above the most frequently prescribed supportive drug for ALD was GI drugs among that the pantoprazole [PPI (81%)] was prescribed most followed by ranitidine [H2 receptor blocker (16%)] and omeprazole PPI (3%), the reason behind most frequent use of pantoprazole in patients is gastric disorder associated with ALD, in the study conducted by VINAYAK S it was found that 78.67% and 71.32% patients were prescribed with pantoprazole 80mg and pantoprazole 40mg respectively.

Whereas in our study vitamins ( optineuron 80%, vitamin K 12% and thiamine 8%) were prescribed to all patient with ALD, a study done by BHANU PRAKASH K et al vitamins(optineuron, vitamin K, B complex, ferrous sulphate) were the second most common drug prescribed in ALD patients, this indicate vitamins are necessary to treat nutritional deficiencies commonly suffered by alcoholic patients.

As liver is important site for fighting against microbes, its damaged lead to increased risk of bacteraemia in these patient requiring antibiotics for therapeutic or prophylactic purpose, in this study ceftriaxone (84%) was most commonly prescribed antibiotic followed by

metronidazole (16%), a study conducted by CHRISTEENA JAMES et al reveal that cephalosporin is most commonly prescribed antibiotic and metronidazole is next frequently prescribed antibiotic.

For treatment of ascites in ALD patients diuretics was prescribed in our study furosemide (72%) was most commonly prescribed than spironolactone (28%) which was in line with the studies done by KOLASANI B P et al where spironolactone and furosemide are common diuretics being prescribed.

Hepato-protectants used to improve the function of liver which was damage in ALD. In our study Among

them ursodeoxycholic acid (65%) is highest prescribed drug followed by silymarin (14%), L-ornithine L- aspartate (14%) and liv52 (7%), a study conducted by KOLASANI B P the liv 52 was the highest prescribed drug followed by urcodeoxycholic acid, silymarin, pentoxifylline, metadoxine.

The present study assessed the complication like acute gastritis, ADS, DM, liver abscess, hypertension, peripheral neuropathy, hepatitis, COPD and anemia. CHRISTEENA JAMES et al conduct a similar study which their assessed the complication like ascites, cirrhosis, portal hypertension, hepatomegaly, hepatic encephalopathy, esophageal varices, hepatocellular carcinoma as well as fatty liver which is associated with ALD.

**CONCLUSION:**

Our prospective observational study analysed for the first time the prescribing pattern of drugs used in patients with ALD and found that males are most prone to ALD than females at the age group 31-40 years. This may be mainly due to the increased alcohol consumption, which is one of the most important predisposing factor for cirrhosis by men in Indian scenario. Base line LFT profiling can be used for screening for alcohol abuse. Acute GI and ADS was found as the most common associated comorbidities with ALD patients. GI drugs are commonly prescribed drugs followed by vitamins and antibiotics, hepatoprotectants like ursodeoxycholic acid, benzodiazepines like Lorazepam were mainly prescribed to minimize the patients symptoms and management of the patients was completely based on symptoms of the disease, thus the morbidity and mortality associated with this disease can be prevented.

**REFERENCES:**

1. Tilg H, Christopher P, Management strategies in alcoholic liver disease. Nature clinical practice

- gastroenterology and hepatology 2007 January 4;4:24-36.
2. Zeebaish S, Hemalatha P, Eswari P, Kodandaraman T, Lakshmi P, Apoorva G. A prospective observational study on prescribing patterns of drugs used in alcoholic liver disease patients at tertiary care teaching hospital. *International Journal of Basic & Clinical Pharmacology* 2017 June;6(6):1386-1392.
  3. Kolasani B P, Sasidharan P, Divyashanthi C M, Jayabal P, Rajaseharan A. Prescribing Pattern Of Drugs in Patients With Alcoholic Liver Disease In A Tertiary Care Hospital. *National Journal of Physiology, Pharmacy and Pharmacology* 2016 December 02;7(5):538-544.
  4. Gururaj G, Murthy P, Girish N, Benegal V. Alcohol related harm: Implications for public health and policy in India. *Indian Journal Of Community Medicine.* 2010;35(2):238-244.
  5. Vihang N, Vahia. *Diagnostic and Statistical Manual of Mental Disorders.* American Psychiatric Association Arlington. 2013 Jul-Sep;55(3): 220-223.
  6. *Global Status Report on Alcohol and Health.* World Health Organization. 2011;286.
  7. Kim W, Brown R, Terrault N, El-Serag H. Burden of liver disease in the United States: Summary of a workshop. *Hepatology.* 2002;36(1):227-42.
  8. Chisholm D, Doran C, Shibuya K, Rehm J. Comparative cost- effectiveness of policy instruments for reducing the global burden of alcohol, tobacco and illicit drug use. *Drug Alcohol Review.* 2006;25:553-565.
  9. Wagenaar A, Salois M, Komro K. Effects of beverage alcohol price and tax levels on drinking: a meta-analysis of 1003 estimates from 112 studies. *Us National Library Of Medicine National Institutes Of Health. Addiction* 2009;104(2):179-190.
  10. Yach D. The origins, development, effects, and future of the WHO Framework Convention on Tobacco Control: a personal perspective. *Lancet* 2014;383(9930):1771–1779.
  11. Zhao J, Stockwell T, Martin G, Macdonald S, Vallance K, Treno A, et al. The relationship between minimum alcohol prices, outlet densities and alcohol-attributable deaths in British Columbia. 2002–09. *Addiction* 2013;108:1059-1069.
  12. Sheron N, Chilcott F, Matthews L, Challoner B, Thomas M. Impact of minimum price per unit of alcohol on patients with liver disease in the UK. *Clin Med* 2014;14:396-403.
  13. Hart C, Morrison D, Batty G, Mitchell R, Davey S. Effect of body mass index and alcohol consumption on liver disease: analysis of data from two prospective cohort studies. *BMJ* 2010;340:1240-1244.
  14. Younossi Z, Henry L. Systematic review: patient-reported outcomes in chronic hepatitis C—the impact of liver disease and new treatment regimens. *Aliment Pharmacol Ther.* 2015 January 23;41:497–520.
  15. Hallager S, Ladelund S, Christensen PB, Kjaer M, ThorupRoegge B, Gronbaek K, et al. Liver-related morbidity and mortality in patients with chronic hepatitis C and cirrhosis with and without sustained virologic response. *Clin Epidemiol* 2017;9:501-516.
  16. Organisation for Economic Co-operation and Development. *Tackling harmful alcohol use: economics and public health policy.* OECD Publishing; 2015 May 12.
  17. Colombo G, Addolorato G, Agabio R. Role of GABA(B) receptor in alcohol dependence: reducing effect of baclofen on alcohol intake and alcohol motivational properties in rats and amelioration of alcohol withdrawal syndrome and alcohol craving in human alcoholics. *Neurotox Res* 2004 January;6(5):403-414.
  18. Addolorato G, Caputo F, Capristo E, Colombo G, Gessa G, Gasbarrini G. Ability of baclofen in reducing alcohol craving and intake: II—Preliminary clinical evidence. *Alcohol Clin Exp Res* 2000 Nov;24(11):67–71.
  19. Flannery B, Garbutt J, Cody M. Baclofen for alcohol dependence: a preliminary open-label study. *Alcohol Clin Exp Res* 2004 Jul 3; 28:1517-1523.
  20. Leggio L, Ferrulli A, Cardone S. Relationship between the hypothalamic- pituitary-thyroid axis and alcohol craving in alcohol-dependent patients: a longitudinal study. *Alcohol Clin Exp Res* 2008 Dec;32(12):2047-2053.
  21. Leggio L, Ferrulli A, Cardone S, et al. Renin and aldosterone but not the natriuretic peptide correlate with obsessive craving in medium-term abstinent alcohol-dependent patients: a longitudinal study. *Alcohol* 2008;42:375-381.
  22. Addolorato G, Caputo F, Capristo E, et al. Baclofen efficacy in reducing alcohol craving and intake: a preliminary double-blind randomized controlled study. *Alcohol* 2002 September;37(5):504–508.
  23. Orman E, Odena G, Bataller R. Alcoholic liver disease: Pathogenesis, management, and novel targets for therapy. *J Gastroenterol Hepatol.* 2013 July 15;28(1):77-84.
  24. O’Shea R, McCullough A. Treatment of alcoholic hepatitis. *Clin Liver Dis.* 2005 Nov 21;9(1):103-134.

25. Dutta S, Beg M, Anjoom M, Varma A, Bawa S. Study of prescribing pattern in diabetesmellitus patients in a tertiary care teaching hospital at Dehradun, Uttarakhand. *Int J Med Sci Public Health*. 2014;3(3):1351-1354.
26. Lischner M, Alexander J, Galambos J. Natural history of alcoholic hepatitis. *Am J Dig Dis*. 1971 June;16(6):481-94.
27. Jurlink D, Mamdani M, Kopp A, Laupacis A. Drug-drug interactions among elderly patients hospitalized for drug toxicity. *Journal of American Medical Association*. 2003 April 2;289(13): 1652-1658.
28. Barve A, Khan R, Marsano L, Ravindra K, Mc Clain C. Treatment of alcoholic liver disease. *Annals of Hepatology* 2007 October 23;7-15.
29. Hatton J, Burton A, Nash H, Munn E, Burgoyne L, Sheron N. Drinking patterns, dependency and life-time drinking history in alcohol-related liver disease. *Journal compilation* 2008 November 26;104:587-592.
30. Bergheima I, McClainb C, Gavin E. Treatment of Alcoholic Liver Disease. Department of Pharmacology and Toxicology and James Graham Brown Cancer Center 2009 February 5;5-16.
31. Raynard B, Balian A, Fallik D, Capron F, Bedossa P, Chaput J, .Risk Factors of Fibrosis in Alcohol-Induced Liver Disease. *Organic Rresearch Article*. 2018 October 24;1-8.
32. Weersink R, Taxis K, Drenth J , Houben E, Metselaar H, Borgsteede S. Prevalence of Drug Prescriptions and Potential Safety in Patients with Cirrhosis: A Retrospective Real-World Study. *Original Research Article*. 2008 Mar 2;42(2)1-8.
33. Upasana Dube et al A retrospective study done on prescribing pattern of drugs in alcohol dependence in a tertiary care hospital .