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Original Research Article

A prospective observational study on prescribing patterns of drugs used in alcoholic liver disease patients at tertiary care teaching hospital

Zeebaish S.*, Hemalatha P., Eswari P. V. S. N., Kodandaraman T., Lakshmi P., Apoorva G.

Department of Pharmacy Practice, Sri Padmavathi School of Pharmacy, Tirupati, Andhra Pradesh, India

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***Correspondence to:**
Dr. Zeebaish S.,
Email: zeebaishpharma@gmail.com

ABSTRACT

Background: Rational drug prescribing can be defined as appropriate drugs prescribed in the right dose, at correct time intervals and for a sufficient duration. Alcoholic Liver Disease (ALD) and its complications are the principle cause for morbidity and mortality rate and accounts for elevated social and economic costs. The drug use will be a challenge for the physicians as there was no specific treatment for ALD, and decisions regarding treatment are critically depends on the symptoms and complications.
Methods: A uni-centric prospective (observational) study was conducted for a period of 6months, to evaluate the current prescribing patterns used in treating ALD. All the patients admitted with diagnosis of ALD in General medicine department, both male and female medical wards were included in the study. General medicine outpatient department, special population such as pregnancy and psychiatry, patients below 18years and those who are not willing to sign in informed consent form was excluded from the study.
Results: Number of males (98.02%) between age group 31-40years (29.6%) was more prone when compared to females (1.77%). Portal hypertension (30.35%) followed by jaundice (11.30%) and Ascites (10.71%) were frequently observed complications associated co-morbidities with ALD. WHO prescribing indicators showed deviation from there standard reference values. Diuretics (15.73%), antibiotics (13.14%), vitamin supplements (11.11%) and antacids (10.13%) categories were the most commonly prescribed for patients. The drugs prescribed from NLEM-2015 (82.11%) shows deviation from standard values.
Conclusions: Futhermore, multi-centered studies should be conducted to draw best results on prescribing patterns of ALD in India.

Keywords: Alcoholic liver disease, Complications, Prescribing patterns, Prospective observational study

INTRODUCTION

The world health organization (WHO) addressed drug utilization as the marketing, distribution, prescription, and use of drugs in a society, considering its consequences, medical, social, and economic. Prescription pattern intents to evaluate aspects related to taking of medicines.[1]

Rational drug prescribing can be defined as appropriate drugs prescribed in the right dose, at correct time intervals and for a sufficient duration. Irrational drug prescription is a common problem in many countries that may account to various legal threats to a prescriber. The assessment of drug utilization is important for clinical, economic and educational purposes. Drug utilization studies aim to provide feedback to the prescriber and to create awareness among them about rational use of medicines.[2]

The liver is one of the largest and most important organs for the well-functioning of other organs, because it performs multiple functions such as production of proteins and enzymes, detoxification, metabolic functions, and the regulation of cholesterol and blood clotting. The liver is primarily responsible for alcohol metabolism; it is especially vulnerable to alcohol related injury which alters the normal homeostasis of the liver.[3,4]

Alcoholic liver disease (ALD) is the principal cause of chronic liver disease all over the globe, ranging from simple steatosis to frank cirrhosis.[5-7] ALD and its

complications are the major cause of morbidity and mortality worldwide.[8] Approximately 1% of total world population i.e. 2million people are affected with ALD. Premature death occurring due to alcohol consumption among world is 3.8% of global mortality and 4.6% of disability adjusted life-years (DALYs).[6] Comparing mortality among men and women it was found that men aged between 35-64years have high mortality rate.[9]

Consumption of 12-24 grams of ethanol per day increases the risk of mortality.[6] The National Institute on Alcohol Abuse and Alcoholism defines standard drink as 11-14gram of alcohol, which corresponds to approximately one drink of 40% spirit, one glass of wine (or) 0.33litre (12-OZ) beer. Hence, a "safe" daily intake of alcohol should not be more than two "drinks".[9] Alcohol consuming for more than 10years (80gram of alcohol per day) will develop liver disease at a rate of nearly 100%.[10]

Mortality increases in direct proportion to the extent of malnutrition, approaching 80% in patient with severe malnutrition. Micronutrients abnormalities, such as hepatic vitamin E depletion or depressed vitamin-A levels may also potentially aggravate liver diseases. The incidence of cirrhosis is low in countries with high intake of saturated fat.[11]

There are very few studies which describe the prescribing patterns of drugs in ALD. The present article is an attempt to gain insight into prescribing patterns of drugs in various complications of ALD including specific therapies at General Medicine department in a tertiary care teaching hospital. In present study, the prescribing patterns of ALD drugs were analyzed by using WHO prescribing core indicators.

METHODS

A Uni-centric Prospective Observational study was conducted in a total of 152 prescriptions of patients diagnosed with alcoholic liver disease in general medicine department in a tertiary care teaching hospital for a period of six months.

Inclusion criteria

- All the patients admitted with diagnosis of ALD in General medicine department, both male and female medical wards.

Exclusion criteria

- General medicine department outpatients.
- Special population include pregnancy and psychiatry.
- Patients below 18years.
- Those who are not willing to sign in informed consent form.

A specially designed proforma and informed consent form are used for collecting data which includes patient demographics, past medical history, past medication history, family, social and surgical history, co-morbidities, diagnosis and present medications prescribed for each patient. The proforma also contains the categorization of errors. The data was obtained from the patient case-profiles. All the prescriptions of the patients in general medicine department diagnosed with ALD were included in this study and are analyzed. The WHO prescribing indicators were used in this study. The ethical clearance was obtained from Institutional Ethical Committee before commencing the study.

RESULTS

A total of 152 patients admitted with the diagnosis of ALD for a period of 6months, were included in the study.

Table 1: Age wise distribution of ALD patients.

Age (years)	Number (152)	Percentage (%)
18-30	21	13.18
31-40	45	29.61
41-50	41	26.97
51-60	26	17.10
61-70	14	9.21
>70	5	3.28
Total	152	100

Table 1 indicates that maximum number of ALD patients was found to be in 31-40 years of age - 45 people (29.6%), followed by 41-50 years of age - 40 people (26.97%), 51-60 years of age - 25 people (17.1%), 18-30 years of age - 14 people (13.81%), 61-70 years of age - 14 people (9.21%) and >70 years of age - 5 people (3.28%).

Table 2: Gender wise distribution.

Gender	No. of patient (n=152)	Percentage (%)
Male	149	98.02%
Female	3	1.97%
Total	152	100%

Table 2 shows that the demographics of study population; this table indicates that the male patients were 149, (98%) were found to be higher than the female patients were 3 (2%).

Alcohol consumption for a period of 6-10 years 36 people were highly affected with ALD (23.68%) followed by 11-15 years 28 people (18.42%), 16-20 years 27 people (17.76%), 1-5 years 20 people (13.15%), 21-25 years 15 people (9.86%), >30 years 13 people (8.55%) and 26-30 years 13 people (8.55%).

Portal hypertension is the major complication associated with ALD (51, 30.35 %,), followed by Jaundice (19, 11.3%), Ascites (18, 10.71%) Alcoholic Hepatitis (14,

8.33%), Hepatorenal Syndrome (12, 7.14%), Hepatic Encephalopathy (12, 7.14%), Anemia (12, 7.14%) were commonly observed complications.

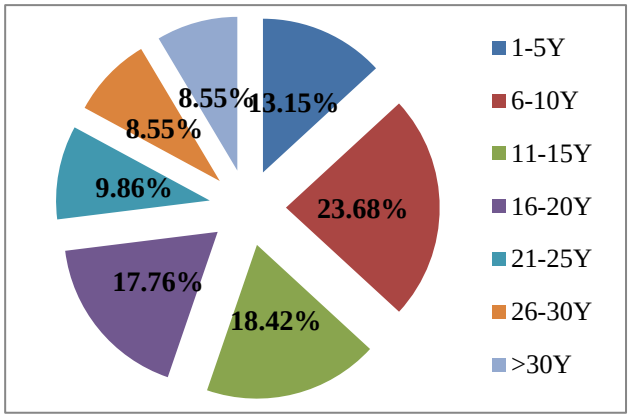

Figure 1: Duration of consumption of alcohol.

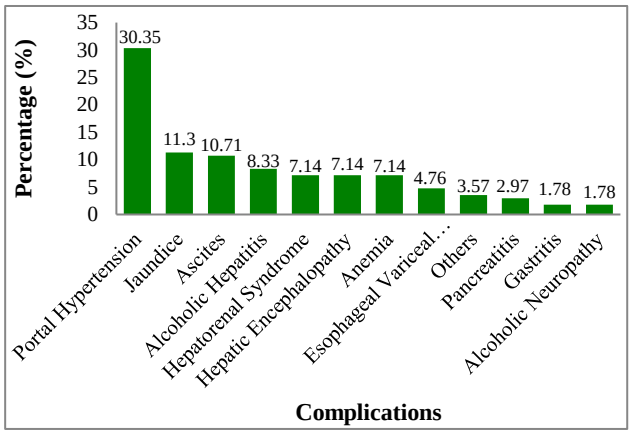

Figure 2: Complications associated with ALD.

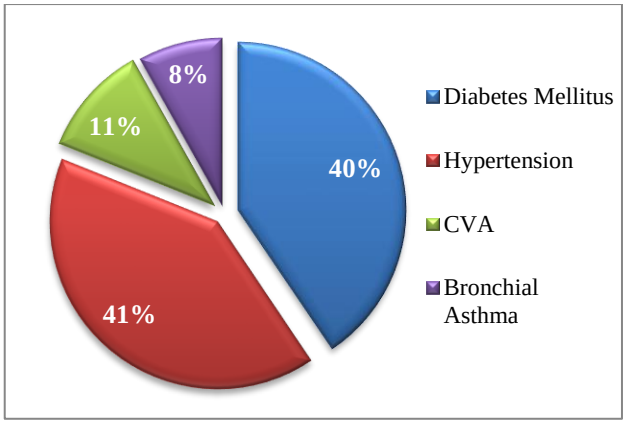

Figure 3: Alcoholic liver diseases with co-morbidities.

The major co-morbidity in ALD patients was Hypertension (15, 41%), followed by Diabetes mellitus (15, 40%), CVA (4, 11%) and Bronchial asthma (3, 8%).

Table 3: Prescribing indicators.

S. No.	Indicator	Value
1.	Total number of prescriptions	152
2.	Total number of drugs prescribed	1430
3.	Average number of drugs per prescription	9.45
4.	Percentage of drugs prescribed by generic name	45.73 %
5.	Percentage of prescriptions with an injection prescribed	95.39 %
6.	Percentage of prescriptions with an antibiotic prescribed	74.34 %
7.	Percentage of drugs prescribed from NLEM-2015	82.11 %

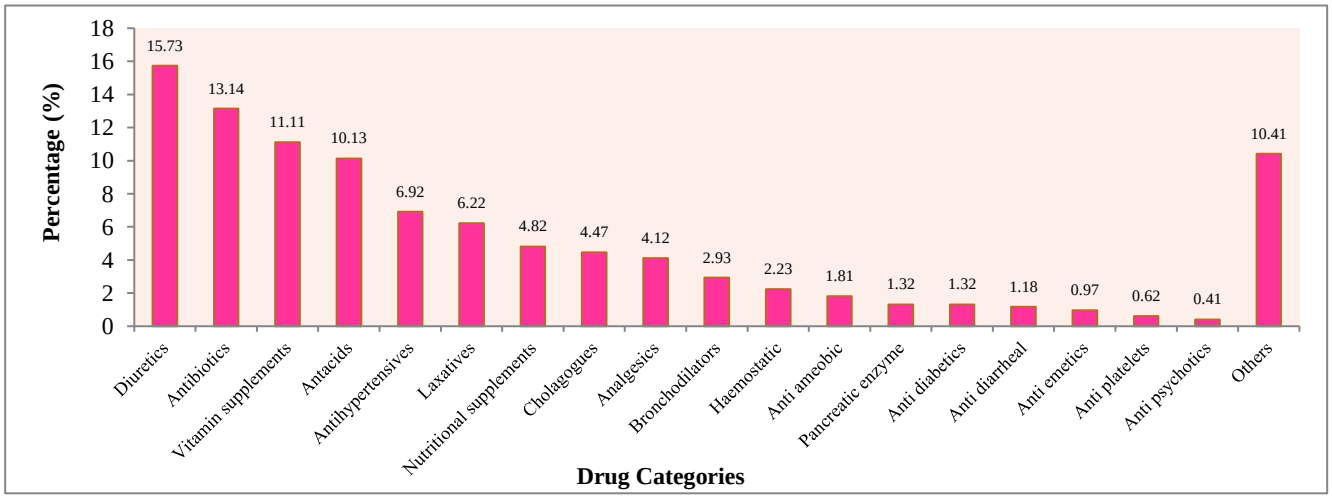

Figure 4: Distribution of prescribed drugs based on their category.

Out of total cases prescribed, diuretics -225 (15.73%) were most commonly prescribed, followed by antibiotics -188 (13.14%), vitamin supplements- 159 (11.11%) and antacids -145 (10.13%).

Table 4: Distribution of diuretics agents.

Diuretics	No. of drugs (n=225)	Percentage (%)
Furosemide	113	50.22
Aldactone	107	47.55
Metalazone	3	1.33
Prazosine	2	0.8
Total	225	100

Under the category of diuretics Furosemide-113 (50.22%) followed by Aldactone -107 (47.55%), Metalazone- 3 (1.33%) and Prazosin -2 (0.8%) were major diuretic agents to treat ALD complications.

Table 5: Distribution of antibiotics.

Antibiotics	No. of drugs (n=188)	Percentage (%)
Ceftriaxone	66	35.10
Norfloxacin	30	15.95
Rifaximin	24	12.76
Cefotaxime	20	10.63
Ciprofloxacin	17	9.04
Amoxyclav	11	5.85
Piperacillin+Tazobactum	10	5.31
Cefixime	4	2.12
Doxycycline	3	1.59
Ampicillin	1	0.53
Amikacin	1	0.53
Meropenam	1	0.53
Total	188	100

Among all the antibiotics prescribes, Ceftriaxone were 66 (35.1%) most commonly prescribed followed by Norfloxacin were 30 (15.95) and Rifaximin 24 (12.76), Cefotaxime were 20 (10.63%), ciprofloxacin were 17 (9.04%), Amoxyclav were 11 (5.85%), Piperacillin+ Tazobactum were 10 (2.12%), Cefixime were 4 (2.12%), doxycycline were 3 (1.59%), ampicillin was 1 (0.53%), Amikacin was 1 (0.53%) and Meropenam was 1 (0.53%).

Table 6: Distribution of vitamin supplements.

Vitamin supplements	No. of drugs (n=159)	Percentage (%)
Vitamin-B_1, B_6 and B_{12}	80	50.31
B-complex	64	40.25
Vitamin A and D	6	3.77
Calcium+D3	4	2.51
Thiamine	2	1.25
Vitamin-C	2	1.25
Neurokind plus	1	0.6
Total	159	100

Vitamin-B_1, B_6 and B_{12} were 80 (50.31%) and B-complex were 64 (40.25%) were the main vitamin supplements to be prescribed followed by vitamin A and D were 6 (3.77%), calcium D_3 were 4 (2.51%), thiamine were 2 (1.25%), vitamin-c were 2 (1.25%) and Neurokind plus was 1 (0.6%).

Table 7: Distribution of antacids.

Antacids	No. of drugs (n=145)	Percentage (%)
Pantoprazole	137	94.4
Aluminium hydroxide	4	2.7
Ranitidine	4	2.7
Total	145	100

The most commonly preferred antacid was Pantoprazole were 137 (94.4%), followed by Aluminium Hydroxide were 4 (2.7%) and Ranitidine were 4 (2.7%).

Table 8: Distribution of anti hypertensives.

Anti hypertensives	No. of drugs (n=99)	Percentage (%)
Propranolol	88	88.88
Amlodipine	5	5.05
Enalapril	2	2.02
Atenolol	2	2.02
Clonidine	1	1.01
Prazosin	1	1.01
Total	99	100

Propranolol were 88 (88.88%) was the most commonly prescribed Anti-Hypertensive agents, used to treat portal hypertension was a major complication in ALD followed by Amlodipine were 5 (5.05%), Enalapri were 2 (2.02%), Atenolol were 2 (2.02%), Clonidine was 1 (1.01%) and Prazosin was 1 (1.01%).

DISCUSSION

Now a day's alcohol consumption is tremendously increasing all over the world. The over use of alcohol is inducing liver disorders among individuals. The alcohol consumption is also increasing the morbidity and mortality rate and accounts for elevated social and economic costs.

A prescription written by a physician may be taken as an indication of doctor's attitude towards the disease and the role of drugs in its treatment. Hence the prescribing pattern of every physician will differ from other. The drug use will be a challenge for the Physicians as there was no specific treatment for ALD, and decisions regarding treatment are critically depends on the symptoms and complications. This study describes the pattern of prescription of drugs used in ALD patients.

A prospective observational study was carried out for 6 months in general medicine department in patent wards of SVRRGG hospital. A total of 152 patients were included in the study. Among total study population 149

patients were male and 3 patients were females. This reveals the majority of male population over females. This may be due to higher consumption of alcohol is most commonly seen in males than females in Indian scenario. These findings are similar to Vinayak S. Jamdade et al, study.[1]

Table 9: Distribution of Laxatives, nutritional supplements, analgesics, haemostatic, anti ameobic, anti diarrheal, anti platelets, anti psychotics, anti diabetics, steroids, cholagogues, anti fungal, pancreatic enzymes and anti emetics.

Class	Drugs	No. of drugs
Laxatives	Lactulose	87
	Bisacodyl	2
Nutritional supplements	Iron and Folic Acid	34
	25% Dextrose	20
	Pottasium Chloride	12
	Folic acid	1
	Zinc	1
	Iron sucrose	1
Analgesics	Paracetamol	43
	Tramadol	12
	Serratio peptidase	3
	Diclofenac	1
Bronchodilators	Salbutamol	18
	Ipratropium Bromide	16
	Theophylline	8
Anti ameobic	Metronidazole	23
	Albendazole	3
Anti diarrheal	Octreotide	15
	Lactic Acid Bacillus	1
	Racecadotril	1
Anti platelets	Aspirin	6
	Clopidogrel	3
Anti psychotic	Amitriptyline	4
	Alprazolam	1
	Diazepam	1
Anti diabetics	Metformin	15
	Insulin	8
	Glimepiride	6
Steroids	Budesonide	1
	Hydrocortisone	1
	Prednisolone	1
Cholagogues	Ursodeoxycholic acid	64
Anti fungals	Fluconazole	2
Pancreatic enzymes	L-Ornithine-L-Aspartate	19
Anti emetics	Ondansetron	14

In the present study, more number of patients are seen between the age of 31-40 years (45 patients, 29.60%), followed by 41-50 years (40, 26.97%). It may be due to increased alcohol consumption will be more in 30-40 years of age groups, because of their stressful life, urban environmental factors and socio-economic factors, which is similar with Vinayak S. Jamdade et al., study.[1]

Among study population, alcohol consumptions for 6-10 years (35, 23.33%) were highly prone to ALD rather than those people who are consuming alcohol for >30 years. These findings show that duration of alcohol consumption does not affects the progression of liver disease, where quantity of alcohol intake may cause the severity of liver disease. Due to some limitations, the data of quantity of alcohol intake were not included in this study. By this reason, we cannot able to provide the accurate explanation for above result.

Portal hypertension (51, 30.55%) was the major complication seen among the study population, followed by Jaundice (19, 11.30%) and Ascites (18, 10.7%). These findings were similar to Meenu Vijayan study.[12] The most common cause of portal hypertension is cirrhosis of liver. Cirrhosis is scarring which accompanies the healing of liver injury caused by hepatitis, alcohol, or other causes of liver damage. In cirrhosis the scar tissue blocks the flow of blood through the liver which leads to increases the blood pressure in portal vein.

In this study, Diabetes Mellitus (15, 40.54%) and Hypertension (15, 40.54%) were the most common co-morbidities which already existed in the patients prior to ALD diagnosis. As alcohol consumption is the main etiological factor for Diabetes Mellitus and Hypertension.

Among the total drugs prescribed i.e., 1430 drugs, number of drugs prescribed in generics names and brand names were found to be 654 (45.73%) and 776 (54.26%) respectively. The most commonly preferred route of administration was found to be oral (832, 58.18%), followed by injections (564, 39.44%) and inhalational (34, 2.37%).

In the present study, the total number of drugs prescribed for 152 patients were 1430 drugs, the average number of drugs per prescription was 9.45, which is much higher than standard WHO prescribing indicators (1.6-1.8). This may be due further complications and other co-morbidities experienced in patients during the treatment period. Percentage of drugs prescribed by generic names was 45.73%, which is found to be much lesser than the standard (100%). The percentage of prescriptions with an injection prescribed was 95.39%, which is higher than the standard (13.4-24.1%). This may possibly due to confidence of physicians as injections shows faster onset of action than oral administration. The percentage of prescriptions with an antibiotic prescribed was found to be 74.34%, which was much higher than standard value (20.0%-26.8%). The percentage of drugs prescribed from NLEM was found to be 82.11%, which is shows deviation from the standard value (100%). This shows that the drugs are prescribed irrationally. These findings are similar to Vinayak S. Jamdade et al., study [(1)] and contrast to Nithya Nandh et al., study.[13]

From the findings of present study, the primary category of drugs prescribed was diuretics (225, 15.73%) followed

by antibiotics (188, 13.14%), vitamin supplements (159, 11.11%) and antacid (145, 10.13%). Furosemide (113, 50.22%) followed by Aldactone (107, 47.55%) were commonly prescribed diuretic agents. These results were similar to M. Isabel Lucena et al study.[14]

In the total usage of antibiotics Ceftriaxone (66, 35.10%) followed by Norfloxacin (30, 15.95%), Rifaximin (24, 12.76%) and Cefotaxime (20, 10.63%). Vitamin- B_1, B_6, and B_{12} (80, 50.31%) followed by B-complex (64, 40.25%) were the major Vitamin supplement prescribed in this study.

From the pattern of drug uses, it was found that Pantoprazole (137, 94.4%) was highly prescribed antacid. This pattern of use might be that inhibition of gastric secretion could help to prevent upper gastro intestinal bleeding related to portal hyper tension. Propranolol (88, 88.88%) was the major Anti-hypertensive agents prescribed to treat portal hypertension.

In the present study, Lactulose (87, 97.75%) was commonly prescribed laxatives in this study. Iron and folic acid (34, 49.27%), followed by 25% Dextrose (20, 28.98%) and Potassium Chloride (12, 17.39%) were frequently used nutritional supplements. Paracetamol (43, 72.88%) and Tramadol (12, 20.33%) were mostly preferred analgesic agents.

From the analysis of the present study, Salbutamol (18, 42.85%) and Ipratropium Bromide (16, 38.09%) were the most preferable bronchodilators. Metronidazole (23, 88%) and Octreotide (15, 88.23%) were the most commonly prescribed Anti-ameobic and Anti-diarrheal drugs respectively.

In the present study Aspirin (6, 66.66%), Amitryptilline (4, 60%) and Metformin (15, 75%) were the majorly used Anti-platelets, anti-psychotics and Anti-diabetics respectively. Other category of drugs such as cholagogues, anti-fungals, pancreatic enzymes and anti-emetic drugs of which Ursodeoxycholic acid, Fluconazole, L-ornithine-L-aspartate and Ondansetron were prescribed respectively. Ursodeoxycholic acid was majorly prescribed drug as it is a liver protectant agent.

Our study states that there is a dose dependent relation of complications, prognostic markers with the amount of alcohol intake but type of alcohol don't have much effect on the complications, morbidity and mortality. The rational prescribing of drugs will be improved by introducing appropriate educational interventions and involvement of clinical pharmacist in prescribing drugs.

CONCLUSION

The drugs prescribed form NLEM-2015 (82.11%) shows deviation from standard values. Furthermore, multi-centered studies to be conducted to draw best results on prescribing patterns of ALD. Abstinence from alcohol reduces the risks of complications and mortality in patients with ALD is the major therapeutic goal. No specific pharmacological therapy for ALD has demonstrated unequivocal efficacy. Increasing the involvement of clinical pharmacist in clinical rounds by promoting rational drug use and drug adherence may improve the quality of health care. There is need for adherence to ALD treatment guidelines and continuing education for the physicians placing emphasis on drug use in ALD patients.

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