

RESEARCH ARTICLE

Prescribing pattern of drugs in patients with alcoholic liver disease in a tertiary care teaching hospital

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ABSTRACT

Background: Although alcoholism is associated with causation of multiple diseases, alcoholic liver disease (ALD) is the most common cause of mortality. Several drugs are being used in patients with ALD. **Aims and Objectives:** The aim of this study is to evaluate the prescribing pattern of drugs used in patients with ALD. **Materials and Methods:** A retrospective, observational study was done by analyzing the medical records of patients with ALD at a tertiary care teaching hospital for 3 months. A total of 146 case records of patients with ALD were reviewed and details such as demographics, specified drugs prescribed with their dose and dosage forms were recorded and analyzed. **Results:** Overall, 1,365 drugs were prescribed for 146 patients, out of which hepatoprotective agents were the most commonly prescribed drugs (19.63%) followed by vitamins and minerals (16.63%) and antiulcer drugs (12.60%). The most commonly prescribed antimicrobial drug was cephalosporin (37.7%), diuretic was spironolactone (58.8%), intravenous (i.v.) fluid was 25% dextrose (45.3%) and for treating the complications like hepatic encephalopathy and variceal bleeding were lactulose (46.9%) and propranolol (80.7%), respectively. Chlordiazepoxide was the most common and the only drug prescribed for treating alcohol withdrawal symptoms. **Conclusion:** Hepatoprotective agents along with vitamins and minerals were the most commonly prescribed drugs for patients with ALD. Corticosteroids were prescribed comparatively less in our study.

KEY WORDS: Alcoholic Liver Disease; Hepatoprotective Drugs; Corticosteroids; Spironolactone; Lactulose; Chlordiazepoxide

INTRODUCTION

Alcoholism, or alcohol use disorder, is defined, according to the diagnostic and statistical manual of mental disorders, 5th edition, as a problematic pattern of alcohol use leading to

clinically significant impairment or psychological distress.^[1] Alcoholism results in an estimated 2.5 million deaths annually worldwide, representing 4% of all mortality.^[2] It is the leading risk factor for mortality for ages 15-59 in males, and the eighth leading risk factor for mortality for all ages in both sexes.^[2]

Although alcoholism is associated with more than 60 diseases, most mortality from alcoholism results from alcoholic liver disease (ALD). ALD includes alcoholic steatosis, alcoholic hepatitis, and alcoholic cirrhosis, in order of increasing severity ALD, moreover, accounts for 40% of mortality from cirrhosis.^[3] Annual mortality for ALD is 4.4/1,00,000 in the

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general population.^[4] Development of ALD is dose-dependent and drinking ≥ 30 g/d of alcohol increases the risk of ALD in both sexes.^[5,6] Women have a greater risk of ALD than men, likely secondary to differences in ethanol metabolism.^[7-10]

Several drugs are currently being used in ALD, which include pentoxifylline, ursodeoxycholic acid (UDCA), metadoxine, corticosteroids and some alternative medicines like Liv 52 and Silymarin but with varied success. In addition, some drugs are used to treat the complications of ALD like antibiotics for infections; lactulose, rifaximin and L-ornithine L-aspartate (LOLA) for encephalopathy; furosemide and spironolactone for ascites and octreotide, propranolol and ethamsylate for variceal bleeding; disulfiram and naltrexone for decreasing the craving and dependence of alcohol; chlordiazepoxide for treating withdrawal symptoms.^[11,12]

The study of prescribing patterns seeks to monitor, evaluate and suggest modifications in practitioners' prescribing habits so as to make medical care rational and cost-effective.^[13] A Medline search of prescribing pattern of drugs in ALD has not shown any positive results. Hence, we planned this study to evaluate the prescribing pattern of drugs used in patients with ALD.

MATERIALS AND METHODS

This retrospective observational study was carried out at a tertiary care teaching hospital. The case record files of all the inpatients of medicine department with a diagnosis of ALD between March 2013 and February 2016 were retrieved from medical records section after obtaining approval from Institutional Ethics Committee. All the procedures followed in this study were in accordance with the Helsinki declaration of 1975, as revised in 2000.

Patients of either sex above 18 years of age and diagnosed to have ALD based on clinical and biochemical evidence during the above-mentioned period were included in the study. Pregnant, lactating and those with malignancy were excluded from the study.

We reviewed the prescriptions of above patients and the details were collected using a specially designed pro forma containing relevant details such as demographics (age, gender), clinical data (symptoms, duration of alcohol consumption, and liver function test [LFT]), and drug data were used. Drug data include drug categories, specific drugs prescribed with their dose, formulation, route and frequency of administration. For simplification, we have divided all the drugs that were prescribed into 12 categories which include.

1. Hepatoprotective drugs
2. Antibiotics
3. Antiulcer drugs

4. Vitamins and minerals
5. i.v. fluids
6. Antiemetics
7. Diuretics
8. Drugs for alcohol withdrawal
9. Drugs for hepatic encephalopathy
10. Drugs for variceal bleeding
11. Corticosteroids
12. Miscellaneous

Statistical analysis was primarily descriptive with all the data expressed as mean \pm standard deviation and as percentages.

RESULTS

A total of 146 prescriptions of in-patients with ALD were analyzed out of which 144 were males and only two were females. The mean age of male patients was 44.9 whereas that for females was 56. The youngest patient was aged 25 years and the oldest patient was aged 70 years. The majority of the patients belonged to 41-50 age group 50 (34.3%) followed closely by 31-40 age group. The mean duration of alcohol intake was 16.96 in males and 21 in female patients (Table 1). Out of the total 146 patients, LFT was available for only 106 patients (Table 2).

On the whole, a total of 1,365 drugs were prescribed for 146 patients with ALD out of which 574 (42.1%) were prescribed by generic name and 791 (57.9%) were prescribed by brand name.

Hepatoprotective agents were the most commonly prescribed drugs with a total of 268 prescriptions (19.63%) followed by vitamins and minerals of 227 prescriptions (16.63%) and antiulcer drugs of 172 prescriptions (12.60%). The least prescribed drugs were corticosteroids (0.01%) (Table 3).

Among the hepatoprotective drugs, Liv 52 (36.9%) and UDCA (36.6%) were the most commonly prescribed

Table 1: Demographic profile of patients with alcoholic liver disease

Parameter	Male	Female
Total number of patients	144	2
Average age (mean \pm SD*) (years)	44.88 \pm 9.88	56 \pm 5.66
Age distribution		
21-30 years	9	-
31-40 years	49	-
41-50 years	50	-
51-60 years	28	2
61-70 years	8	-
Average years of alcohol consumption (mean \pm SD) (years)	16.96 \pm 8.76	21 \pm 12.73

SD: *Standard Deviation

followed by metadoxine (12.7%), pentoxifylline (9.0%), and silymarin (4.9%) being the least prescribed (Figure 1).

In vitamin and mineral preparations, which were the second most common category of drugs prescribed, parenteral multivitamin formulation (30%) was the most commonly prescribed which was closely followed by parenteral vitamin K (28.2%). Oral folic acid was the least commonly prescribed in this group (Figure 2).

Antiulcer drugs were the third most common drugs prescribed and among them parenterally (i.m.) given pantoprazole (47.7%) was the most commonly prescribed drug followed by oral ranitidine (Figure 3).

Out of the antimicrobial drugs, cephalosporins were highest prescribed drugs (37.7%) with parenteral cefotaxime being the most commonly prescribed followed by metronidazole (25.4%) and fluoroquinolones (18.8%). Linezolid (0.1%) was least prescribed of all the antibiotics (Figure 4).

Table 2: Baseline LFT profile of patients with alcoholic liver disease

Parameter	Mean±SD*
Albumin (g/dl)	3.06±0.73
Total bilirubin (mg/dl)	2.78±3.04
Direct bilirubin (mg/dl)	1.33±1.86
Indirect bilirubin (mg/dl)	1.46±1.47
SGOT (U/l)	90.16±70.24
SGPT (U/l)	78.91±67.92
ALP (U/l)	199.63±136.24
Prothrombin time (s)	6.36±0.99

SD*: Standard Deviation, SGOT: Serum glutamate oxaloacetate transaminase, SGPT: Serum glutamate pyruvate transaminase, ALP: Alkaline phosphatase, LFT: Liver function test

Table 3: Number of drugs prescribed in patients with alcoholic liver disease - category wise

Drug category	Number of prescriptions (%)
Hepatoprotective agents	268 (19.63)
Antimicrobial agents	138 (10.11)
Antiulcer drugs	172 (12.60)
Vitamin and mineral preparations	227 (16.63)
i.v. fluids	64 (4.69)
Antiemetics	42 (3.08)
Diuretics	119 (8.72)
Drugs for alcohol withdrawal	39 (2.86)
Drugs for hepatic encephalopathy	160 (11.72)
Drugs for variceal bleeding	62 (4.54)
Corticosteroids	01 (0.01)
Miscellaneous	73 (5.35)
Total	1365 (100)

The most commonly used i.v. fluid for ALD patients was 25% dextrose (45.3%) followed by ringer lactate (23.4%) and the least prescribed was 5% dextrose (3.1%) (Figure 5). Among diuretics, the most commonly prescribed drug was spironolactone (58.8%), followed by furosemide (41.2%) (Figure 6).

Among the antiemetics, the most commonly prescribed drug was parenterally given ondansetron (61.9%) followed by metoclopramide (28.6%) while the least prescribed was domperidone (9.5%). Chlordiazepoxide was one and only drug prescribed for treating alcohol withdrawal symptoms.

Among the drugs that were used for treating complications, lactulose (46.9%) in the syrup form was the most commonly prescribed which was closely followed by LOLA (41.9%) for treating hepatic encephalopathy (Figure 7). Rifaximin (11.2%) was the least prescribed. For treating variceal bleeding, oral propranolol (80.7%) was the most commonly prescribed drug followed distantly by ethamsylate (8.1%), parenteral octreotide (6.5%). Adrenochrome and tranexamic acid

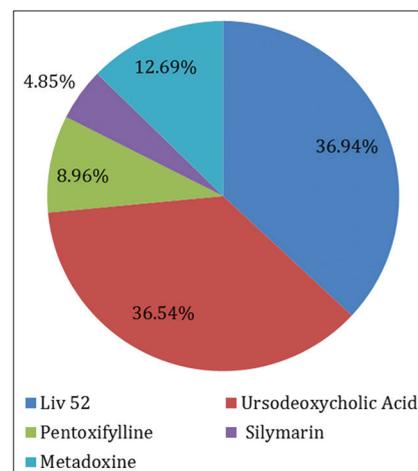


Figure 1: Prescription pattern of hepatoprotective agents in patients with alcoholic liver disease

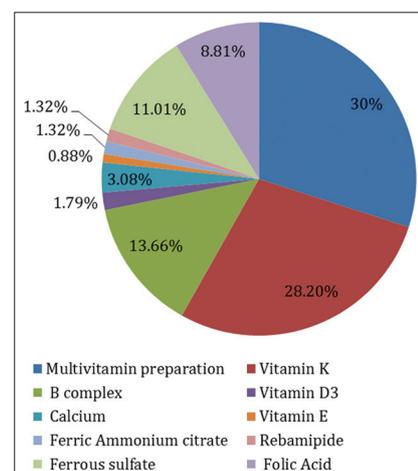


Figure 2: Prescription pattern of vitamin and mineral preparations in patients with alcoholic liver disease

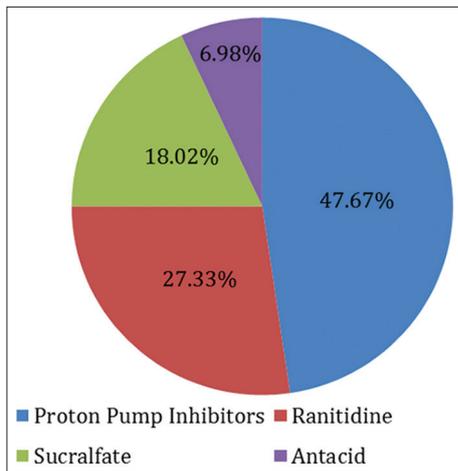


Figure 3: Prescription pattern of antiulcer drugs in patients with alcoholic liver disease

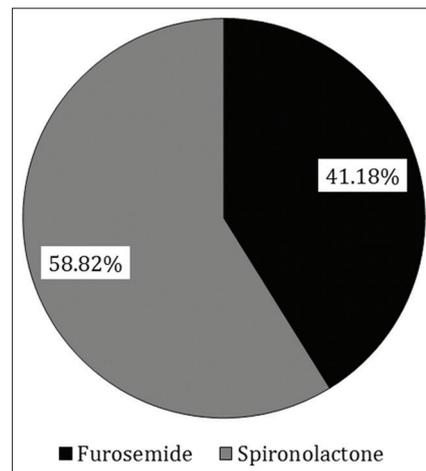


Figure 6: Prescription pattern of diuretics in patients with alcoholic liver disease

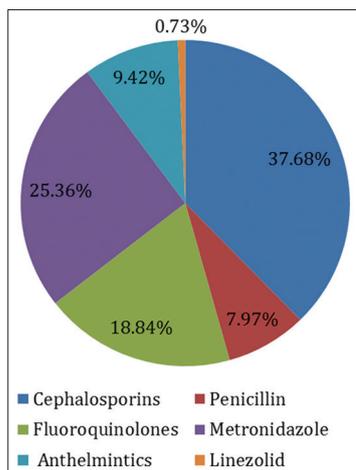


Figure 4: Prescription pattern of antimicrobial agents in patients with alcoholic liver disease

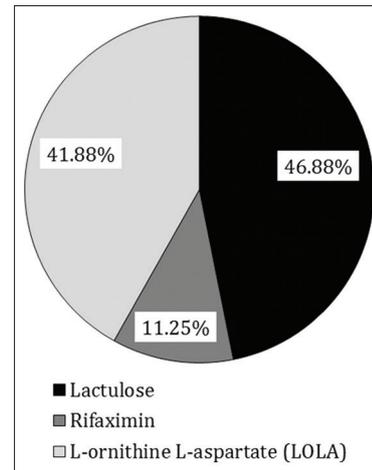


Figure 7: Prescription pattern of drugs for hepatic encephalopathy in patients with alcoholic liver disease

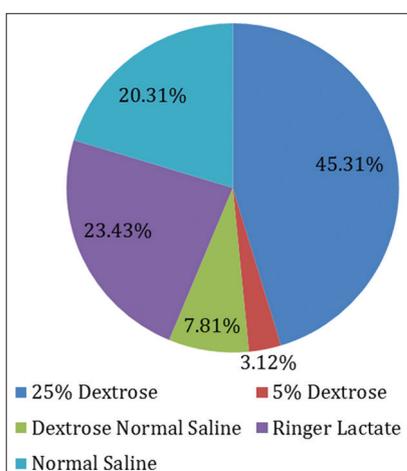


Figure 5: Prescription pattern of intravenous fluids in patients with alcoholic liver disease

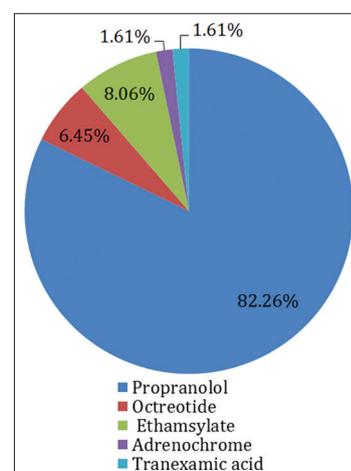


Figure 8: Prescription pattern of drugs for variceal bleeding in patients with alcoholic liver disease

(both 1.6% each) were the least prescribed drugs in this group (Figure 8).

In our study, corticosteroids are prescribed very less and we have found that only one patient (0.01%) was given

corticosteroids. Among the drugs used in the miscellaneous category which included analgesics-antipyretics, probiotics, laxatives and enzyme preparations, analgesic-antipyretic-anti-inflammatory agents (46.9%) were most commonly prescribed followed by digestive enzymes (21.9%).

DISCUSSION

To the best of our knowledge, there is no study which evaluated the prescribing pattern of drugs used in ALD patients worldwide. Our study, for the first time, comprehensively analyzed all the drugs that were prescribed to patients with ALD.

Even though, many studies indicate that women develop liver disease by consuming lower amount of alcohol and for shorter periods of time compared to men,^[7,14] in our study, only two out of a total of 146 patients who were included in the study were females (Table 1). This may be due to sociocultural aspects of this country, where almost exclusively males are involved in alcohol intake. This is in contrast to the previous study^[15] where the peak age distribution of alcoholic hepatitis was between 40 and 60 years. This can be explained by the habit of consuming the alcohol from a very early age in this region compared to other parts of the country where we have observed that many people gave history of starting consuming alcohol from 10 to 12 years itself.

Hepatoprotective drugs were the most commonly prescribed category in our study (Table 3) and as can be expected they are used to improve the function of liver which is deranged in ALD. Among them, Liv 52 was the highest prescribed drug (Figure 1). It is a polyherbal preparation and in both experimental^[16,17] and clinical studies^[18,19] has shown that it offers significant protection against alcohol-induced hepatic damage because of its antioxidant, anti-inflammatory, and immunosuppressant actions.^[20] The reason for its widespread usage might be due to its above-mentioned therapeutic effects with minimal adverse effects.

Prescription of Liv 52 was closely followed by that of UDCA, a nontoxic, hydrophilic bile acid with cytoprotective, antiapoptotic, immunomodulatory effects^[21] followed by metadoxine, an antioxidant^[22] and pentoxifylline, a nonspecific phosphodiesterase inhibitor which slows down the inflammation and subsequent fibrosis of liver by inhibiting tumor necrosis factor (TNF- α).^[23] According to recent guidelines, it can be used in combination with enteral nutrition, as a reasonable alternative to corticosteroids in patients with severe ALD and may be preferred in patients with infection or renal failure/hepatorenal syndrome.^[24,25]

Silymarin, an alternative medicine for patients with liver disease was the least prescribed hepatoprotective agent. In animal models, its protective effects in several forms

of liver injury have been shown and the mechanisms including anti-inflammatory, antioxidative, antifibrotic, and immunomodulating effects are thought to explain the benefit of silymarin in ALD.^[26]

As nutritional deficiency is very common in these patients, prescription of vitamin and mineral preparations was seen to be common in our study and overall they are the second most commonly prescribed drugs after hepatoprotectives. Antiulcer drugs were the third most commonly prescribed drugs in our study as long-term intake of alcohol damages the gastric mucosa to a large extent.

As liver is an important site for fighting against microbes, its damage leads to increased risk of bacteremia in these patients requiring antibiotics for therapeutic or prophylactic purpose.^[27] Cephalosporins and metronidazole were the most common antibiotics prescribed which can be explained as these drugs cover the mixed infection with anaerobes of peritonitis that is common in these patients. This is in accordance with the guidelines so that drugs like macrolide antibiotics, including erythromycin, azithromycin, clindamycin along with chloramphenicol, and tetracyclines as these drugs should be avoided in patients with ALD.

About 25% dextrose and ringer lactate were the commonly used i.v. fluids which might be explained by the fact that both nutritional deficiencies and electrolyte abnormalities will be common in these patients. For treatment of ascites in ALD patients, diuretics should be given and in our study, as spironolactone, a potassium sparing diuretic was more commonly prescribed than the loop diuretic furosemide as there will be secondary hyperaldosteronism in ALD patients and a drug like spironolactone which acts by inhibiting aldosterone receptor will be more effective compared to the other diuretic classes, even better than furosemide.^[28]

Complications such as hepatic encephalopathy and variceal bleeding are an important part of ALD patients and treatment of them is of utmost importance to prevent morbidity and mortality. As raised ammonia level is the cause for hepatic encephalopathy, lactulose which inhibits intestinal ammonia production by a number of mechanisms^[29,30] and LOLA were the commonly prescribed drugs in our study. Ornithine and aspartate being the important substrates in the metabolic conversion of ammonia to urea and glutamine, respectively, LOLA provides for both of these ammonia detoxification pathways.^[31]

The mainstay of the pharmacological approach to the primary prophylaxis of variceal hemorrhage has been propranolol and for control of acute variceal bleeding, two major classes of drugs are vasopressin or its analogs and somatostatin or its analogs. As most of the patients of our study are stable and do not have active bleeding, oral propranolol, which can control the bleeding efficiently was prescribed the most in our study compared to other drugs.

Steroids are indicated in two conditions of ALD: One is in severe ALD, defined by Maddrey discriminant function ≥ 32 and the other in patients with ALD with hepatic encephalopathy. Steroids are one of the oldest and most investigated drugs for severe alcoholic hepatitis but their benefit in ALD remains to be contradictory.^[32,33] They act by reducing inflammatory cytokines such as TNF- α , intercellular adhesion molecule 1, interleukin (IL)-6 and IL-8^[34,35] as inflammation is a major component of ALD pathogenesis. Although many agents have been used across different studies, prednisolone is preferred over prednisone as the latter requires conversion within the liver to its active form, prednisolone. In our study, corticosteroids are prescribed very less and we have found that only one patient (0.01%) was given corticosteroids.

Even though there are many new drugs available for patients with ALD that include anti-TNF- α agents (such as infliximab and etanercept) and other anticytokine agents, they were not prescribed in our study which may be explained because of the cost constraints in a developing country like India. There were no drugs prescribed for decreasing the craving and dependence of alcohol such as naltrexone, acamprosate, disulfiram, topiramate, and baclofen which was expected as all these patients were inpatients getting treated for ALD and these drugs would be prescribed only after their discharge from the hospital.

The strength of this study lies in the fact that it was the first of its kind which studied about the drugs prescribed in patients with ALD. The other important strength of our study is that we have comprehensively analyzed all the drugs used in patients with ALD along with the drug class, dosage form, and dose prescribed. Limitations include a relatively small sample size, the study being unicentric in nature, we cannot compare the regional variations in drug prescribing and also we did not evaluate factors like adherence to treatment guidelines and concerns of the patients about the adverse effects of drugs during the treatment. As this was the first study to analyze the prescribing pattern of drugs in ALD patients, we were unable to compare the results of our study with any of the previous similar studies.

CONCLUSION

Our retrospective observational study analyzed for the first time the prescribing pattern of drugs used in patients with ALD and found that hepatoprotective agents are the most commonly prescribed drugs followed by vitamin and mineral preparations and antiulcer drugs. Cephalosporins were the most commonly prescribed antimicrobial drugs. Lactulose and propranolol were the most commonly prescribed drugs for treating the complications such as hepatic encephalopathy and variceal bleeding, respectively. The most commonly prescribed diuretic was spironolactone and the most commonly used i.v. fluid was 25% dextrose. Chlordiazepoxide was the only drug prescribed for treating alcohol withdrawal

symptoms. Corticosteroids were prescribed less in our study. New drugs like anti-TNF- α agents which have better efficacy, also were not seen in the prescriptions probably because of the cost constraints.

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