Drug Utilization Pattern of Patients with Alcoholic Liver Disease in Jayanagar General Hospital, Bangalore, India

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Abstract

Objective: The study aimed to evaluate the utilization pattern of drugs in patients with Alcoholic Liver Disease. **Methodology:** A prospective observational study was done by analyzing the medical records of patients with ALD at Jayanagar general hospital for 6 months. A total of 80 case records of ALD patients was reviewed and details including specified demographic drugs prescribed were recorded and analyzed. A prospective study also called a historic cohort study, a longitudinal cohort study used in psychological and medical investigations. The data is collected from existing records and can immediately be analyzed. **Result:** overall 567 drugs were prescribed for 80 patients, out of which GI drugs were the most frequently prescribed drugs (20.49%) followed by vitamins (18.91%), antibiotics (14.39%), diuretics (11.61%), hapatoprotectants (10.60%), saline (8.85%), benzodiazepines (8.08%), and less commonly anti-emetics (7.07%). The most commonly prescribed antimicrobial, diuretic, and hepatoprotective drugs were ceftriaxone (84%), furosemide (72%), and ursodeoxycholic acid (65%), respectively. **Conclusion:** GI Drugs along with vitamins and antibiotics were the most commonly prescribed drugs for patients with ALD.

Keywords: Alcoholic Liver Disease; Vitamins; Demography; LFT profile; Ursodeoxycholic acid.

INTRODUCTION

According to the world health organization (WHO), drug utilization is the process of prescription, distribution, and use of drugs in a country, regarding its outcomes, medical, social, and economic consequences. [1, 2] It is a system of ongoing and systematic criteria on the basis of the assessment of drug use that helps to ensure drugs are used properly. By assessing drug utilization, it collects, analyzes, and interprets drug usage patterns to improve the quality of drug use and patient outcomes. 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 chief cause of chronic liver disease all over the world, which can be started from simple steatosis to cirrhosis [3]. ALD and its complications are the major cause of mortality and morbidity worldwide. Approximately two million people are suffering from ALD. Alcoholism is associated with over 60 diseases, but most mortality of alcoholism results from ALD. In the last 10 years, the rate of alcohol consumption in India has been increased as high as 106.7%. As per WHO researches about 30% of Indians consume alcohol, around 50% of which are hazardous drinkers and the mean age is from 17 to 28 years. Generally, alcohol is responsible for 5.9% of global mortality worldwide and 2.5 million deaths per year. Men aged between 35-64 years have a high-risk rate. Alcohol consumption for more than 10 years (80 grams of alcohol per day) will develop the liver disease at a rate of nearly 100% [4].

According to ICD-10, ADS is a cluster of cognitive, behavioral, and physiological phenomena in which the use of alcohol is a much higher priority for a given individual than other behaviors that were once more valuable. Cirrhosis is the histological development of regenerative nodules that are surrounded by fibrous bands due to chronic liver damage, leading to end-stage liver disease and portal hypertension. About 2 billion people around the world consume alcoholic beverages on a regular basis, and more than 76 million suffer from AUD [5].

There are many complications associated with alcohol abuse such as alcohol intoxication, alcohol tolerance, alcohol withdrawal, and alcohol dependence. Diseases associated with alcohol abuse can be prevented with moderate consumption and behavioral modifications should be

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considered. The management of patient conditions also depends upon the existing comorbidities. This gives an idea to generate our study. The laboratory findings that are frequently elevated in ALD are SGOT, SGPT, AST, Bilirubin, etc. [6]. The general clinical features include vomiting, nausea, abdominal pain, 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 disease severity. This study is mainly focused on drug utilization patterns 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. The extent of liver damage depends on the quantity, duration, and pattern of drinking. Comorbidities, nutritional factors, genetic, gender, interaction with host factors (i.e., gut microbiota), and hepatitis, are the main factors that influence the ALD development and the progression. Health professionals and health policies should target people who are not yet addicted to or dependent on alcohol but drink beyond a safe level. We conducted a prospective investigation to identify the risk, nature, and treatment of ALD. The study of drug utilization pattern seeks to evaluate, monitor, and suggest required modifications in prescribing patterns so has to make the therapy rational and cost-effective [4].

METHODOLOGY

The study was performed in Jayanagar General Hospital, Bangalore, which is a 400 bedded secondary care hospital. After obtaining permission from the Institutional Ethics Committee, a prospective, cross-sectional study is carried out for a period of 6 months in Jayanagar General Hospital. All the patients admitted to general medicine with alcoholic liver disease and patients visiting General Medicine OPD with alcohol dependence syndrome were included in the study. Patients' social history, location, and demographic details; clinical data including duration of hospital stay, radiographic

details, laboratory profile, diagnosis, symptoms, etc.; therapeutic data including the name, route, dose, and frequency of the drug; the duration of therapy; and other relevant details were recorded in a suitably-designed individual case record form by reviewing their prescriptions, medical records, and caretakers.

The assessment was recorded in a specifically-designed patient profile form, design, and distribution of a patient information leaflet. The pattern of usage of drugs, their utilization pattern, the correlation between age and alcohol consumption will be studied. A prospective study also called a historic cohort study is a longitudinal cohort study used in psychological and medical studies. The data is collected from existing records and can immediately be analyzed. In order to record necessary data from the sources mentioned above, a self-designed Case Record Form was designed based on the data required for the study, which included patient's medication history, social history, family history, demography, and clinical parameters like blood pressure and blood sugar levels, hepatoprotective therapy, and adjunct therapy. Detailed patient information was obtained from the 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 tests, etc. are noted below. Details about the pharmacotherapy with respect to the use of drug utilization patterns of patients with alcoholic liver disease were collected.

RESULT AND DISCUSSION

A total of 80 ALD patients admitted to the medical department in Jayanagar general hospital for a period of 6 months was analyzed, out of which 73 patients were male (91%) and 7 were female (9%) (Table 1). This indicates that the burden of alcoholic liver disease (ALD) is more in male patients.

| Table 1: Demographic Profile of Patients with Alcoholic Liver Disease | | | | | | | | |
|---|--------|------------|--------|------------|--------|------------|--|--|
| AGE | MALES | | FEMALE | | TOTAL | | | |
| (YEARS) | NUMBER | PERCENTAGE | NUMBER | PERCENTAGE | NUMBER | PERCENTAGE | | |
| 21-30 | 19 | 26.02 | 0 | 0 | 19 | 23.75 | | |
| 31-40 | 26 | 35.64 | 5 | 71.43 | 31 | 38.75 | | |
| 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 | | |

In the present study, in the age group of 31-40 years, the majority of the female patients (71.43%) were at risk for ALD followed by males (35.64%); while, in the age group of 21-30 years, it was 26.02% for males and 0% for females; for the age group of 41-50 years, it was 19.17% for males and 0% for females, and it was less comparatively among patients above 50 years with the rate of 19.17% and 28.57% for males and females, respectively.

Alkaline phosphatase (ALP), serum glutamic pyruvic transaminase (SGPT), serum glutamic oxalo-acetic transaminase (SGOT), total bilirubin, direct bilirubin, and albumin, as well as serum protein, were elevated in the disease. SGOT, SGPT, and ALP levels were at high while albumin and protein found to be a slight increase or decrease in their level. Baseline LFT are shown in Table 2.

| Table 2: Baseline Lft Profile in Alcoholic Liver Disease | | | | |
|---|--|--|--|--|
| PARAMETER | MEAN SD | | | |
| albumin (g/dl) | 3.93 ± 1.31 | | | |
| serum protein(g/dl) | 6.66 ± 1.62 | | | |
| Total bilirubin(mg/dl) | 2.38 ± 1.89 | | | |
| Direct bilirubin(mg/dl) | 1.32 ± 1.43 | | | |
| SGOT(U/I) | 67.72 ± 42.91 | | | |
| SGPT(U/I) | 59.73 ± 31.99 | | | |
| ALP(U/I) | 217.1 ± 90.52 | | | |
| SD: Standard Deviation, SGOT: ser transaminase, SGPT: serum glutama | rum glutamate oxaloacetate ute pyruvate transaminase, | | | |

LFT:

liver

function

phosphatase,

ALP:

alkaline

| Table 3: Prescription pattern of drugs in ALD | | | | | |
|---|------------|--------|--|--|--|
| Drugs | Percentage | Number | | | |
| antibiotics | 14.39 | 82 | | | |
| diuretics | 11.61 | 66 | | | |
| hepatoprotections | 10.6 | 60 | | | |
| vitamins | 18.91 | 107 | | | |
| anti-emetics | 7.07 | 40 | | | |
| benzodiazepines | 8.08 | 46 | | | |
| GI drugs | 20.49 | 116 | | | |
| saline | 8.85 | 50 | | | |

Among the hepatoprotective agents ursodeoxycholic acid (65%) was the most commonly prescribed drug followed by Silymarin (14%), L-ornithine L-aspartate LA (14%), and LIV 52 (7%) being the least prescribed. GI drugs are the most frequently prescribed medicines and among them parentally and orally given pantoprazole (81%) followed by ranitidine (16%) and omeprazole (3%). Among diuretics, the most commonly prescribed drugs were furosemide (72%), followed by spironolactone (28%). In vitamins, which were the second most common category of drugs prescribed, parenteral optineurin (80%) was mostly prescribed, and vitamin k (12%) and thiamine (8%) were the least prescribed vitamins. Out of antimicrobials drugs, ceftriaxone was the highest prescribed drug (84%) followed by metronidazole (16%).

The most common comorbidities found with ALD were acute gastritis (29.31%), ADS alcohol dependent syndrome (18.97%), and moderately liver abscess (10.34%), respectively, and the least complications were anemia (5.17%) and peripheral neuropathy (5.17%).

Table 4: Comorbidities associated with alcoholic liver disease

Complication Associated With ALD percentage

Acute gastritis 29.31

alcohol dependent syndrome 18.97

| peripheral neuropathy | 5.17 |
|-----------------------|-------|
| COPD | 5.17 |
| dm | 10.34 |
| anemia | 5.17 |
| liver abscess | 10.34 |
| hepatitis | 5.17 |
| hypertension | 10.34 |
| | |

Table 5: Prescription pattern of drugs in a patient with alcoholic liver disease

| Prescription pattern | Drugs | Percentage |
|----------------------|----------------------|------------|
| Hepatoprotections | Ursodeoxycholic acid | 65 |
| | Silymarin | 14 |
| | Liv 52 | 7 |
| | Lola | 14 |
| Gi | Pantoprazole | 81 |
| | Ranitidine | 16 |
| | Omeprazole | 3 |
| Diuretics | Furosemide | 72 |
| | Spironolactone | 28 |
| Vitamins | Optineurin | 8 |
| | Vitamin k | 12 |
| | Thiamine | 80 |
| Antimicrobials | Ceftriaxone | 84 |
| | Metronidazole | 16 |

In the total 80 cases with ALD, the majority of patients belonged to the age group of 31-40 years (38.75%), followed by age group of 21-30 years (23.75%), above 50 (20%), and 41-50 (17.5%), respectively. **JAMDADEA**, et al. [7] conducted a similar study and revealed that the majority of patients were in the age groups of 31-40 years followed by 41-50 years, 18-30 years, 51-60 years, and 61-70 years, respectively. Another study made by VIJAYAN et al. [8] showed that the majority of patients belonged to the age group of 51-60 years followed by 41-50 years, 21-30 years, and 71-80 years, respectively. In a study done by **Gröber et al** [9], it was explained that GI drugs were the most commonly prescribed drug followed by vitamins, hepatoprotectives, antibiotics, diuretics, benzodiazepines, as per study made by KOLASANI et al. [10] who showed that hepatoprotective drugs were the most commonly prescribed drugs followed by antibiotics, GI drugs, 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 the most frequently use of pantoprazole in patients is a gastric disorder associated with ALD. In the study conducted by **Gröber** [9], it was found that 78.67% and 71.32% of patients were prescribed with 80mg pantoprazole and 40mg pantoprazole, respectively.

In our study, vitamins (optineurin 80%, vitamin K, 12%, and thiamin 8%) were prescribed to all patients with ALD. A study done by **Reddy et al.** [11] vitamins (optineurin, vitamin K, B complex, and ferrous sulfate) were the second most common drugs prescribed in ALD patients. This indicates that vitamins are necessary to treat nutritional deficiencies commonly suffered by alcoholic patients. As the 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 purposes. In this study, ceftriaxone (84%) was the most commonly prescribed antibiotic followed by metronidazole (16%). A study conducted by Fujita et al. [12] it was revealed that cephalosporin is the most commonly prescribed antibiotic and metronidazole is the next frequently prescribed antibiotic.

For the treatment of ascites in ALD patients, diuretics were prescribed in our study furosemide (72%) was more commonly prescribed than spironolactone (28%), which was in line with the studies done by **KOLASANI** et al. [10] where spironolactone and furosemide were common diuretics prescribed. Hepato-protectants were used to improve the function of the liver, damaged in ALD. In our study, ursodeoxycholic acid (65%) was the highest prescribed drug followed by silymarin (14%), L-ornithine L-aspartate (14%), and liv52 (7%). In a study conducted by **KOLASANI** [10], liv52 was the highest prescribed drug followed by ursodeoxycholic acid, silymarin, pentoxifylline, and methadone.

CONCLUSION

Alcoholic liver disease is a serious consequence of drinking alcohol and alcohol dependence is one of the more serious public health issues in the world. It not only affects health but also it is a social and economic burden. Pharmacotherapy is the mainstay of treatment along with behavioral therapy for alcohol addiction. The present study was done to analyze the prescribing pattern of drugs in alcohol liver disease aiming to evaluate the drug utilization pattern of drugs in patients with ALD. A prospective observational study was done by analyzing the medical records of patients with ALD at Jayanagar general hospital for 6 months. A total of 80 case records of patients with ALD was reviewed and details such as demographic, and specified drugs prescribed were recorded and analyzed. 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%), hepatoprotection (10.60%), saline (8.85%), benzodiazepines (8.08%) and less commonly anti-emetics (7.07%). The most commonly prescribed antimicrobial diuretic, and hepatoprotective drugs

Ceftriaxone (84%), Furosemide (72%), Ursodeoxycholic acid (65%), respectively. Our prospective observational study analyzed 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 in the age group of 31-40 years. This may be mainly due to the increased alcohol consumption, which is one of the most important predisposing factors for cirrhosis by men in the Indian scenario. Baseline LFT profiling can be used for screening for alcohol abuse. Acute GI and ADS were found as the most common associated comorbidities with ALD patients. GI **drugs** were commonly prescribed drugs followed by vitamins and antibiotics. Hepatoprotectants like ursodeoxycholic acid, and 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.

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