



STUDY OF DRUG PRESCRIPTION PATTERN AND SAFETY OF DIFFERENT DRUGS USED IN ALCOHOL-RELATED CHRONIC LIVER DISEASE IN GSVM COLLEGE, KANPUR: A TERTIARY CARE HOSPITAL

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Abstract:

Introduction: Management of alcohol-related chronic liver disease involves a multifaceted approach, including lifestyle modification, abstinence from alcohol, and pharmacotherapy. Despite the availability of various treatments, there is a lack of consensus on the optimal drug regimen and a need for localized data on drug prescription patterns and their safety profiles.

Aims & Objectives: This study was planned to evaluate drug prescription pattern and safety of different drugs used in patients with alcohol-related chronic liver disease.

Materials & Methods: An observational prospective study was conducted by the Department of Pharmacology, in collaboration with the Department of Medicine, G.S.V.M. Medical College, Kanpur. Prescriptions were collected and further studied. All basic details and prescribed drugs were collected and entered in predesigned proforma.

Results: The gender distribution indicated a significant male predominance (99.45%). The drug prescription pattern revealed an average of 6.67 drugs per prescription.

Antibiotics were prescribed at 1.39 per encounter, with 65.08% prescribed using generic names and 90.14% sourced from government supplies. Number of drugs prescribed by generic name were 779 (65.08%) drugs and most according to essential list of medicines i.e., 80.86% which increases rationality of our prescription. In present study, causality assessment of ADRs according to Naranjo scale suggested that of total 19 patients who had ADRs, 22(43.14%) were probable and 29(56.86%) were possible.

Conclusion: While the study provides a detailed snapshot of current practices and safety issues, ongoing efforts are required to enhance drug prescription practices and ensure the safest and most effective treatment strategies for patients with alcohol-related chronic liver disease.

Further research is needed to refine drug prescription strategies, evaluate long-term outcomes, and explore the efficacy of emerging therapies.

Keywords: Drug prescription, Safety, Alcohol-Related Chronic Liver Disease

INTRODUCTION:

Chronic liver disease (CLD) resulting from alcohol consumption is a significant global health concern, manifesting as a spectrum of liver damage from fatty liver to cirrhosis and hepatocellular carcinoma. According to the World Health Organization, alcohol-related liver disease is a major cause of morbidity and mortality, contributing to a considerable burden on healthcare systems worldwide (WHO, 2020) **1**. In India, the prevalence of alcohol-related liver disease is rising, exacerbated by increasing alcohol consumption and inadequate early intervention. **2**

Although alcoholism relates to more than 60 diseases, alcoholic liver disease is the leading cause of death from Alcoholic Liver Disease (ALD). ALD encompasses, in a sequence of increasing severity, alcoholic steatosis, alcoholic hepatitis, and alcoholic cirrhosis. Moreover, ALD accounts for 40% of cirrhosis-related mortality. The annual death rate for ALD in the general population is 44 per one million **3-4**. The development of ALD is dose-dependent, and alcohol consumption of 30 g/d raises the risk of ALD in both sexes. Women have a higher risk of ALD than men, presumably due to variations in ethanol metabolism.**5**

Management of alcohol-related chronic liver disease involves a multifaceted approach, including lifestyle modification, abstinence from alcohol, and pharmacotherapy. The choice of medication plays a crucial role in managing symptoms, preventing progression, and addressing complications. Several treatments, including pentoxifylline, ursodeoxycholic acid (UDCA), metadoxine, corticosteroids, and alternative therapies such as Liv 52 and Silymarin, are presently used to treat ALD, with varying degrees of efficacy. In addition, certain medications are used to treat the complications of ALD, such as antibiotics for infections; lactulose, rifaximin, and L-ornithine L-aspartate (LOLA) for encephalopathy; furosemide and spironolactone for ascites; octreotide, propranolol, and ethamsylate for variceal bleeding; disulfiram and naltrexone.**8-9**

Despite the availability of these treatments, there is a lack of consensus on the optimal drug regimen and a need for localized data on drug prescription pattern and their safety profiles.

The study of drug prescription pattern in tertiary care settings, such as GSVM College Hospital in Kanpur, provides valuable insights into the real-world application of therapeutic strategies and their outcomes. This research aims to evaluate the patterns of drug use and assess the safety of various drugs prescribed for alcohol-related chronic liver disease at GSVM College Hospital. By analyzing prescription trends and adverse effects, this study seeks to identify gaps in treatment protocols and propose recommendations for improving patient care.

Understanding local drug Prescription pattern and safety profiles can aid in optimizing treatment regimens, minimizing adverse effects, and enhancing the overall management of alcohol-related liver disease. This study contributes to a critical evaluation of current practices and supports evidence-based adjustments to therapeutic strategies.

With this background this study aims to evaluate drug prescription pattern and safety of different drugs used in patients with alcohol-related chronic liver disease with the following objectives;

- To find the demographic profile of alcohol-related CLD patients.
- To assess drug prescription pattern in alcohol-related CLD patients.
- To assess the safety of drugs by adverse drug reactions for medicines prescribed for alcohol-related CLD patients.

MATERIAL & METHODS

An observational prospective study was conducted by the Department of Pharmacology, in collaboration with the Department of Medicine, G.S.V.M. Medical College, Kanpur, and associated hospitals from February 2023 to May 2024. The study included patients above 18 years of age of either sex suffering from Alcohol related Chronic Liver Disease diagnosed and confirmed by physicians after

taking written informed consent. However, patient with an incomplete medical record, critically ill patients, patient with carcinoma, concurrent major psychiatric illness, concurrent major medical illness, or any other chronic disease, Immuno-compromised patients, Pregnant or lactating women and patients not willing to participate or do not give consent for the study were excluded from the study.

Sample size was calculated using Cochran's Formula, $n = Z^2 PQ/d^2$ considering prevalence of ALD and 5% level of significance, by which we obtained minimum sample size was 182. [10]

On considering inclusion and exclusion criteria, total of 182 study subjects diagnosed with ALD were selected after obtaining written consent for the present study. 25 patients were lost to follow up and 29 patients died during the study period, which were not considered in the analysis as they would have influenced the study result. Prescriptions of each study subject were collected and further studied. All basic details of patient and prescribed drugs were collected and recorded using a structured data collection

sheet prepared for study having the following sections;

Section A includes patient name, age, gender, education, occupation, income, accompanied attendant details etc.

Section B includes details of various drugs and their drug prescription pattern indicators were filled as follows

Commonly used drugs in patients of alcohol-related chronic liver disease in the Medicine department.

Average number of drugs per prescription.

Number of drugs used by the injectable route.

Number of antibiotics prescribed.

Total dose and duration of administration of each drug.

Number of Drugs Prescribed by generic name.

Percentage of drugs prescribed from the essential drugs list

Percentage of drugs taken from government supply

Section D includes 10-questions to assess the Safety in subjects by using Naranjo Probability Scale.

Interpretation:

Definite: ≥ 9

Probable: 5- 8

Possible: 1-4

Doubtful: 0

Follow-up was done at 4 weeks, 8 weeks, 12 weeks, 16 weeks. At each follow up a detailed history of drug prescription pattern and Safety of different drugs used was assessed.

Statistical Method:

The data of the present study has been recorded and after its proper validation, checked for error; coding & data compilation, and segregation were done in MS Excel. Statistical Package for the Social Sciences (SPSS) software version 23.0 was used for statistical analysis.

Categorical variables have presented in number and percentage (%) and continuous variables presented as mean \pm SD and median. The chi-square test was used to determine the association among categorical variables. The quantitative data were expressed as Mean \pm SD. P value < 0.05 was considered statistically significant.

RESULTS

Most of the study subjects were above 35 years (71.43%) and presented in late in life. Age group 36-45 years (75, 41.21%) and above 45 years were 55 (30.22%). The mean age \pm S.D. was 44.17 ± 6.17 years.

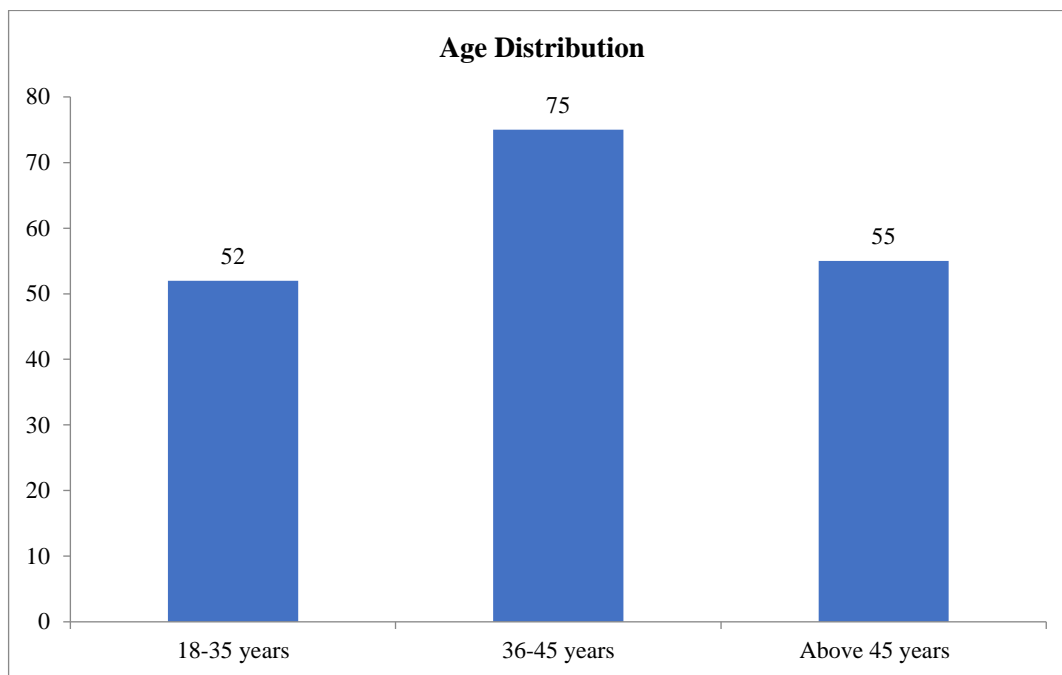


Figure 1: Bar diagram showing the distribution of Age

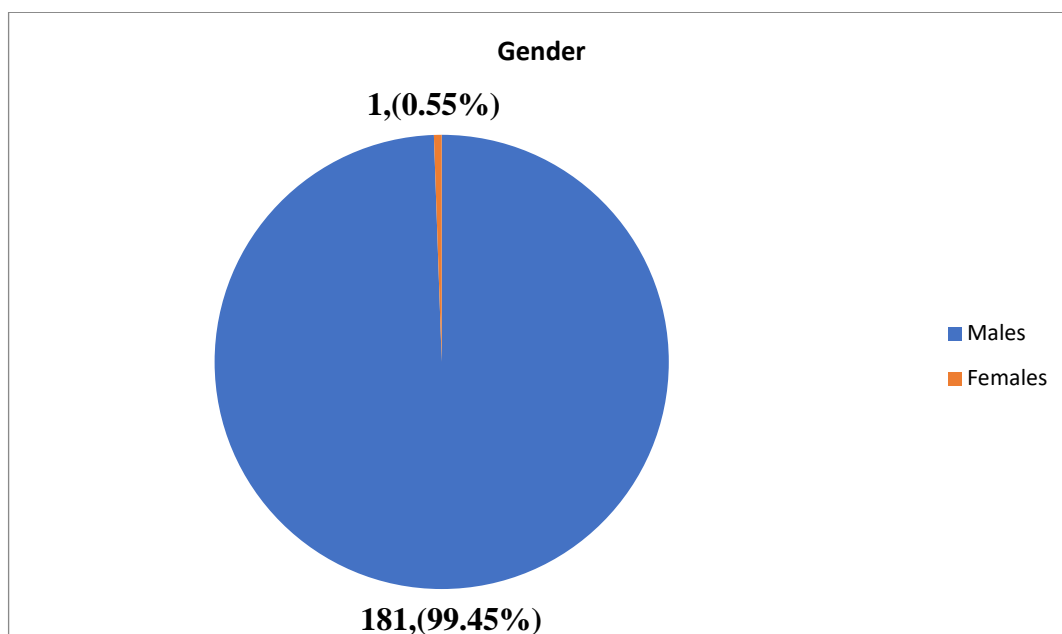


Figure 2: Distribution of study subjects according to Gender

Figure 2 shows the distribution by gender of study patients and showed that there was male predominance with 181 (99.45%) subjects and female 1(0.55%).

Table 1: Distribution of occupation of patients

Occupation	Frequency (n=182)	Percentage (%)
Business/Shopkeeper	35	19.23
Driver	22	12.09
Farmer	12	6.59
Government Job	15	8.24

Labor/Daily wages	36	19.78
Professional/Private Job	53	29.12
Unemployed/Dependent	9	4.95

The above Table 1 provides information on the occupational distribution of 182 patients. Among them, the largest group, comprising 53 patients or 29.12%, is engaged in professional or private sector jobs. The second largest group includes 36 patients (19.78%) who work as laborers or daily wage earners. Additionally, 35 patients (19.23%) are business owners or shopkeepers, while 22 patients (12.09%) work as drivers. A smaller proportion of the patients, 15 in total (8.24%), hold government jobs. The number of patients working as farmers is relatively low, with 12 patients making up 6.59% of the sample. Lastly, 9 patients (4.95%) are unemployed or dependent.

DRUG PRESCRIPTION PATTERN IN STUDY PATIENTS

In the present study, the drug prescription pattern of 182 study patients was evaluated using the following quality indicators of drug use and parameters are observed as follows;

Drug prescription pattern as per WHO

In present study prescription of 182 study patients were analyzed and observed for various indicators of drug prescription pattern as per WHO. It is observed that total fifteen types of drugs were prescribed to the patients. The total number of prescribed drugs were 1197 and an average number of drugs per prescription was found 6.67. Out of total prescribed drugs, four different antibiotics drugs were prescribed and total antibiotic prescribed were 253 and average number of antibiotics prescribed were 1.39. Total prescribed drugs as injectable were 521 and average number of antibiotics prescribed were 2.86.

The table outlines key patterns in drug prescription based on WHO indicators. A total of 1,197 drugs were prescribed, averaging 6.67 drugs per encounter. Among these, antibiotics were prescribed at an average of 1.39 per encounter, with 253 antibiotics prescribed in total. Injectable drugs were also commonly prescribed, with an average of 2.86 per encounter, totalling 521 prescriptions. Oral drugs were prescribed at an average of 3.71 per encounter, accounting for 676 prescriptions overall. Furthermore, a significant portion of these prescriptions—65.08%—were written using generic names, with 779 drugs prescribed in this manner. Prescriptions from the WHO's Essential Drugs List were prevalent, making up 80.86% of the total, or 968 drugs.

Additionally, a large majority of the drugs, 90.14% (or 1,079 drugs), were sourced from government supplies. This data highlights a strong adherence to prescribing essential and generic medications, with a substantial reliance on government-supplied drugs.

Table 2: Drug prescription pattern as per WHO

WHO INDICATORS	FREQUENCY	INFERENCE
Total and Average number drugs prescribed	1197	6.67
Average number of antibiotic drugs prescribed	253	1.39
Average number of injectable drugs prescribed	521	2.86
Average number of oral drugs per encounter	676	3.71

Percentage of drugs prescribed by generic name	779	65.08
Percentage of drugs prescribed from the essential drugs list	968	80.86
Percentage of drugs taken from government supply	1079	90.14

Four drugs were prescribed in 20 encounters, accounting for 10.99% of the total. Five drugs were prescribed in 58 encounters, making up 31.87% of the total. Six drugs were prescribed in 15 encounters, representing 8.24% of the total. Seven drugs were prescribed in 17 encounters, which is 9.34% of the total. Eight drugs were prescribed in 38 encounters, constituting 20.88% of the total. Nine drugs were prescribed in 26 encounters, equaling 14.29% of the total. Ten drugs were prescribed in 8 encounters, comprising 4.40% of the total.

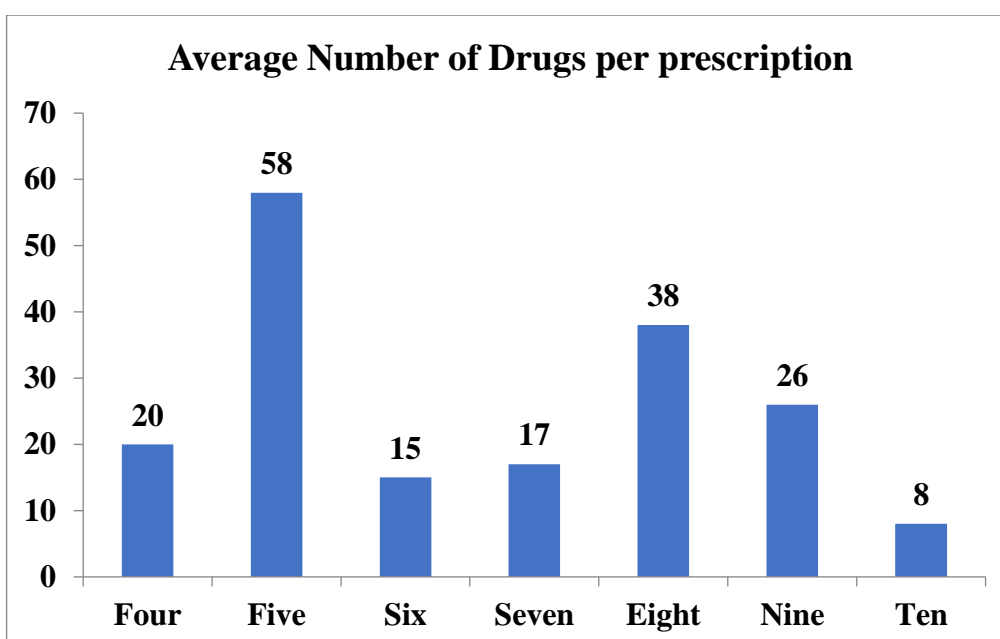


Figure 3: Distribution by Average Number of Drugs per prescription encounter

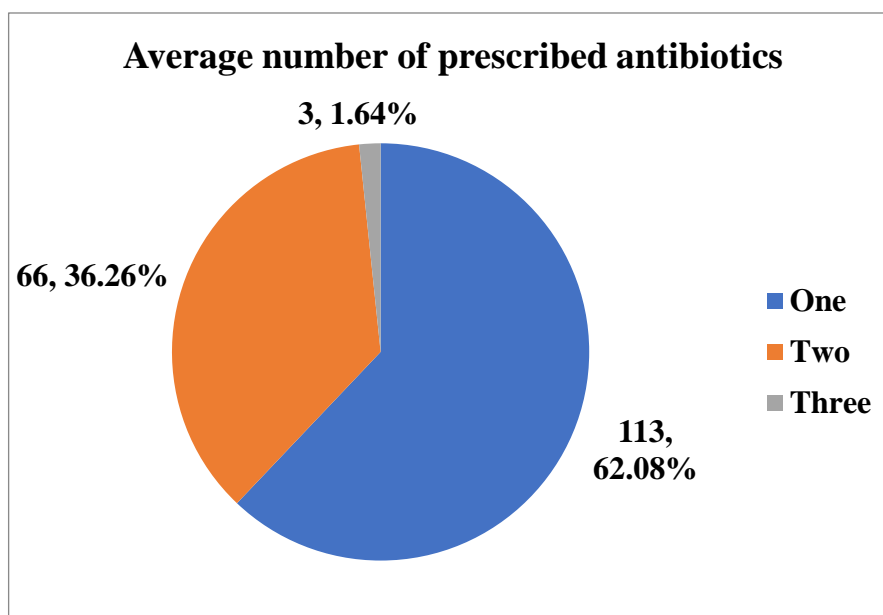


Figure 4: Distribution by Average Number of antibiotics drugs

In present study analyzing the average number of prescribed antibiotics per prescription encounter, which included a total of 182 encounters, the results were as follows: One antibiotic was prescribed in 113 encounters, representing 62.08% of the total. Two antibiotics were prescribed in 66 encounters, accounting for 36.26% of the total. Finally, three antibiotics were prescribed in 3 encounters, making up 1.64% of the total.

SAFETY OF DRUGS FOR ALCOHOL-RELATED CHRONIC LIVER DISEASE

The safety of prescribed drugs used for alcohol-related chronic liver disease is assessed by the Naranjo Adverse Drug Reaction Probability Scale. Side effects and reported Adverse Drug Reactions: In this study, the various side effects and adverse drug reactions due to drug administration were observed and recorded.

No major adverse reaction was noted in this study with any drugs used for alcohol-related chronic liver disease. Total 19 (10.44%) study patients with various ADRs were reported in the study due to prescribed drugs for alcohol-related chronic liver diseases. Common reported ADRs in the study patients received drugs were Abdominal discomfort, Nausea/Vomiting, Bloating, Flatulence, Dizziness, Headache, Hypotension, Fatigue.

In present study, causality assessment of ADRs according to Naranjo scale suggested that of total 19 patients who had ADRs, 22(43.14%) were probable and 29(56.86%) were possible according to Naranjo causality assessment scale. and shows results of Causality assessment of ADRs by Naranjo scale Causality Assessment by Naranjo scale.

Table 3: Distribution of Reported ADR due to prescribed drugs

Reported ADR	Frequency*	Percentage (%)
Abdominal Discomfort	7	13.73
Nausea/Vomiting	3	5.88
Dizziness	9	17.65
Flatulence	8	15.69
Bloating	8	15.69
Hypotension	3	5.88
Headache	7	13.73
Fever/Chills	4	7.84
Fatigue	2	3.92

***Multiple Responses**

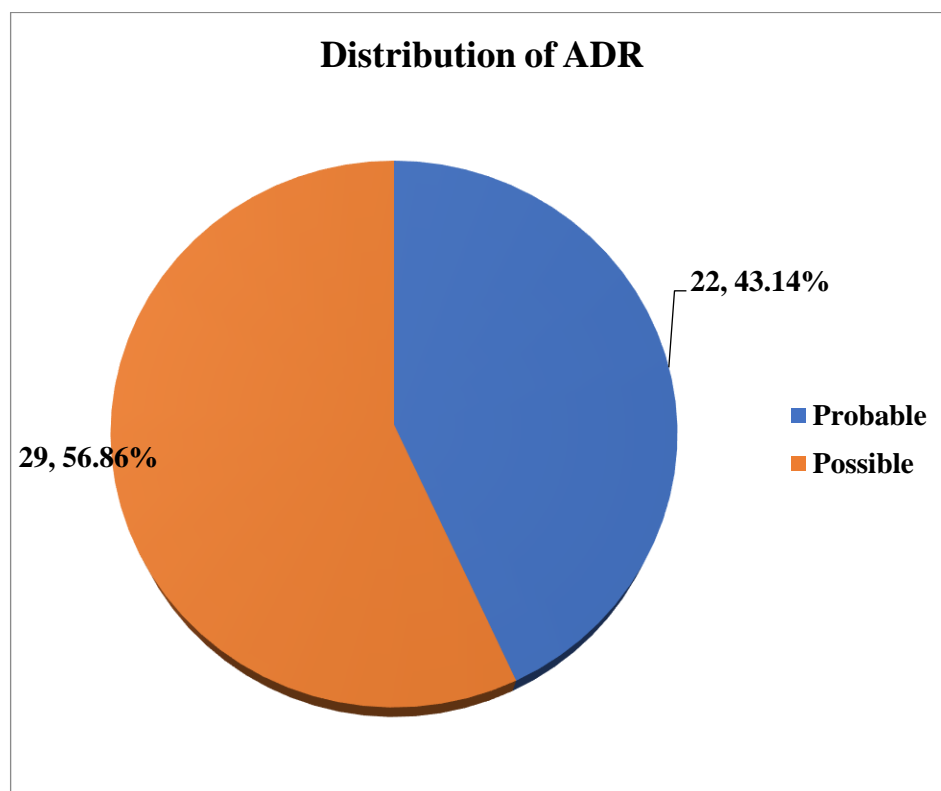


Figure 5: Distribution of causality assessment of ADRs by Naranjo scale

DISCUSSION

Among the 182 alcohol-related chronic liver disease patients, most of them were older than 35 years (71.43%), which was similar to the study conducted by **Arathy PC et al.11**. According to **Jamdadea, et al. 12** 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.13** 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. Males were affected predominantly than females with 99.45%. These findings were consistent with a similar study done by **Huma S et al.14** among CLD patients in which males (91%) were more predominant than females. Similarly, in a study conducted by **Patil. A. M et al.15** on Alcoholic liver cirrhosis in hospital-based patients, the prevalence of ALD based on Gender wise distribution was highest in males compared to females and also according to age-wise distribution prevalence was highest in age group of above 30 years. In contrast, a study by **Becker U et al.16** and **Fuchs CS et al.17** indicate that women develop liver disease by consuming lower amounts of alcohol and for shorter periods compared to men. This is due to males' greater susceptibility to suffer from ALD when compared to female subjects due to increased prevalence of alcohol intake in the adult male group of society.

In the present study, the total number of prescribed drugs were 1197 and an average number of drugs per prescription was found 6.67. A study conducted by **Kolasani et al.18** on Prescription pattern of drugs in patients with ALD where 1365 drugs were prescribed, 19.63% hepatoprotective drugs, 16.65% vitamins and minerals followed by 12.60% of antiulcer drugs were used among patients. Out of total prescribed drugs, four different antibiotics drugs were prescribed and total antibiotic-prescribed were 253 and average number of antibiotics prescribed were 1.39. 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.**18**

In our study total prescribed drugs as injectable were 521 and average number of antibiotics prescribed were 2.86. Number of drugs prescribed by generic name were 779 (65.08%) drugs and most according to essential list of medicines i.e., 80.86% which increases rationality of our prescription. It was also found that the most of the patients got the drugs from government supply or our institute (90.14%) which was found to be similar with study carried out by **Sathish Kumar.V et al.19**.

In present study, the average number of prescribed antibiotics per prescription encounter, which included a total of 182 encounters, One antibiotic was prescribed in 113 encounters, representing 62.08% of the total. Two antibiotics were prescribed in 66 encounters, accounting for 36.26% of the total. Finally, three antibiotics were prescribed in 3 encounters, making up 1.64% of the total. Finally, three antibiotics were prescribed in 3 encounters, making up 1.64% of the total.

Bajaj and colleagues 20 has compared the outcomes of patients who received early antibiotic treatment upon hospital admission to those who received antibiotics only if an infection was clinically suspected. The results of the study revealed no significant difference in overall survival between the two groups, challenging the routine use of early antibiotic therapy in this patient population. Furthermore, Bajaj and colleagues found that prophylactic antibiotics may disrupt the natural phage–bacterial balance, leading to shifts in phage populations and potentially affecting microbial diversity. While antibiotic prophylaxis has proven beneficial, the careful consideration of individual patient characteristics is essential. Factors such as antibiotic resistance patterns, renal function, and the presence of comorbidities should be evaluated when selecting the appropriate prophylactic regimen. In this study, the various side effects and adverse drug reactions due to drug administration were observed and recorded. No major adverse reaction was noted in this study with any drugs used for alcohol-related chronic liver disease. Total 19 (10.44%) study patients were reported with various ADRs in the study due to prescribed drugs for alcohol-related chronic liver diseases. Common reported ADRs in the study patients received drugs were Abdominal discomfort, Nausea/Vomiting, Bloating, Flatulence, Dizziness, Headache, Hypotension, Fatigue.

In a study conducted by **Franz CC, et al.21**, patients with liver cirrhosis, 20% of the drugs are dosed incorrectly and almost 30% of patients with cirrhosis suffer ADRs. It is estimated that nearly 80% of these ADRs could be prevented. This is to be noted that patients with cirrhosis are more vulnerable to certain adverse drug reactions (ADRs), such as effects on coagulation, hepatotoxicity or nephrotoxicity.**22,23**. A federally funded National Viral Hepatitis Control Program is operational in India since 2018 that includes both preventive (vaccination, blood safety) and early detection: linkage-to-care (screening at-risk population, provision of drugs, surveillance of Alcohol related CLD) strategies **24**. Further, a national NAFLD control program has just been launched in 2021 with activities that integrate liver disease control more broadly into other non-communicable diseases control program.

The most important strength of our study is that we have broadly analyzed all the medications prescribed in patients with ALD, along with drug class, pattern of drug prescription and dosage forms. The small number of female subjects in our study it clearly demonstrates a link between gender and medication adherence, and we also couldn't assess factors such as patient's concerns about drug side effects throughout treatment.

RECOMMENDATIONS

1. Enhanced Drug Monitoring and Safety Measures

- Implement routine monitoring protocols for liver function tests to assess the impact of medications on liver health. This helps in early detection of adverse effects and adjustment of therapy as needed.
- Use drug-specific safety profiles to guide treatment decisions, especially for medications with known hepatotoxicity.

2. Personalized Treatment Plans

- Tailor drug therapy based on individual patient profiles, including the severity of liver disease, comorbid conditions, and potential drug interactions. This personalized approach helps in optimizing therapeutic efficacy and minimizing adverse effects.
- Consider dose adjustments or alternative therapies for patients with advanced liver disease to prevent drug accumulation and toxicity.

3. Medication Review and Optimization

- Regularly review all medications a patient is taking, including over-the-counter drugs and supplements, to avoid potential interactions and redundancies. This is crucial for managing polypharmacy and ensuring that each drug contributes positively to the treatment plan.
- Emphasize the use of drugs with a well-established safety profile in chronic liver disease and avoid those with high hepatotoxic potential unless absolutely necessary.

4. Patient Education and Support

- Educate patients about the importance of adherence to prescribed therapies and the potential side effects of medications. Provide clear instructions on how to take medications, recognize signs of adverse reactions, and when to seek medical help.
- Offer support resources such as counseling and liver disease education programs to help patients understand their condition and the role of medications in their treatment.

5. Research and Evidence-Based Practice

- Encourage ongoing research to assess the efficacy and safety of new and existing drugs in the context of alcohol-related chronic liver disease. This includes participating in clinical trials and staying updated with recent advances in pharmacotherapy.
- Promote the use of evidence-based guidelines for the treatment of chronic liver disease to standardize care and ensure that all patients receive the most effective and safest treatment options.

LIMITATIONS

1. Sample Size and Generalizability

- **Limited Sample Size:** The study may be limited by a small sample size, which can affect the statistical power of the findings and may not fully represent the broader population of patients with alcohol-related chronic liver disease.
- **Regional Bias:** The study results may not be generalizable to other regions or healthcare settings, as patient demographics, healthcare practices, and drug availability can vary widely.

2. Drug Interaction and Comorbidities

- **Complex Drug Interactions:** The presence of multiple comorbid conditions and the use of various medications can complicate the assessment of drug safety and efficacy, making it challenging to attribute adverse effects to specific drugs.
- **Polypharmacy:** The use of multiple medications may obscure the effects of individual drugs and complicate the evaluation of their safety and effectiveness.

3. Variability in Treatment Protocols

- **Inconsistent Treatment Protocols:** Variations in treatment protocols among healthcare providers at the tertiary care hospital could lead to inconsistencies in drug prescription patterns and affect the study's findings.
- **Lack of Standardization:** Differences in clinical practice guidelines and individual treatment decisions can impact the comparability of results across patients.

4. Short Study Duration

- **Limited Follow-Up:** A short study duration may not capture long-term effects of drug therapy, including delayed adverse reactions or long-term benefits.
- **Acute Phase Focus:** If the study focuses on an acute phase of treatment, it may not account for the chronic management aspects and long-term safety of medications.

Acknowledging these limitations is crucial for interpreting the findings of the study accurately and for identifying areas where future research can improve upon the current understanding of drug prescription pattern and safety in alcohol-related chronic liver disease.

CONCLUSION

While the study provides a detailed snapshot of current practices and safety issues, ongoing efforts are required to enhance drug prescription practices and ensure the safest and most effective treatment strategies for patients with alcohol-related chronic liver disease. Further research is needed to refine drug prescription strategies, evaluate long-term outcomes, and explore the efficacy of emerging therapies. Large-scale studies with diverse populations and longer follow-up periods will provide more comprehensive insights into the optimal management of alcohol-related chronic liver disease.

Financial support and Sponsorship : Nil

Conflicts of Interest : There are no conflicts of interest

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