A PROSPECTIVE CROSS-SECTIONAL OBSERVATIONAL STUDY USING W.H.O. PRESCRIBING INDICATORS IN ALCOHOLIC LIVER DISEASE IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Background: Alcoholic liver disease (ALD) includes alcoholic steatosis, alcoholic hepatitis, and alcoholic cirrhosis. In our study, the W.H.O. core Prescribing indicators are used to assess rational drug use(RDU) and to evaluate drug prescribing patterns. **Objectives:** The main objective of our study is to assess the prescription pattern using W.H.O. core prescribing indicators in ALD patients. **Methodology:** This prospective cross-sectional observational study was conducted for a period of 6 months among ALD patients. The data collected from 150 enrolled subjects, was analysed statistically as per W.H.O. prescribing indicators and compared with standard W.H.O. values and reported. **Results:** During the study period, 649 drugs were prescribed to 150 outpatients. The average number of drugs per encounter was found to be 4.33 which indicates polypharmacy, drugs prescribed in the generic name were found to be 53% which does not meet the W.H.O. ideal value, use of antibiotics and injections which were found to be 14.79% and 19.2% respectively which are in optimal value. The drugs which were prescribed from NLEM-2015 were found to be 60.1%. **Conclusion:** Our study suggests that there is a need for the conduct of seminars, workshops, and regular training programs to get the values of core prescribing indicators within standard values led by the W.H.O. to ensure RDU. There is a need for standard treatment guidelines, availability of essential drug lists, and drug information centers. There is a need to increase the involvement of clinical pharmacists in clinical rounds which promotes RDU and hospital policies.

KEYPOINTS: ALD, W.H.O. core prescribing indicators, RDU, NLEM-2015, polypharmacy.

INTRODUCTION

Alcoholic liver disease (ALD) is one of the main causes of chronic liver disease (CLD) worldwide and it accounts for up to 48% of cirrhosis-associated deaths in the United States.

ALD includes alcoholic steatosis, alcoholic hepatitis, and alcoholic cirrhosis.[1] Where, alcoholic steatosis (fatty liver) is an accumulation of a mild-severe amount of fat in hepatocytes which is reversible in nature, followed by Alcoholic Hepatitis develops acutely, usually following a bout of heavy drinking, repeated episodes of alcoholic hepatitis superimposed on pre-existing fatty liver.[I] Alcoholic Cirrhosis is a diffuse injury to the liver characterized by fibrosis and conversion of normal hepatic architecture into structurally abnormal nodules the result is the destruction of hepatocytes and their replacement by fibrous tissue.[II]

Initially, it is asymptomatic then gradually develops hepatomegaly, splenomegaly, pruritus, jaundice, spider angiomata, palmar erythema, encephalopathy, ascites, and edema.[II] If untreated, ALD may lead to complications like portal hypertension, variceal bleeding, ascites, spontaneous bacterial peritonitis, and hepatic encephalopathy.[II]

Epidemiology

A recent report from the World Health Organization (WHO) indicates that 3.3 million deaths (6% of all global deaths) are attributable to alcohol use and that alcohol abuse is one of the risk factors in about 50% of cases of cirrhosis.[1] Cirrhosis is one of the leading causes of mortality and morbidity across the world. It ranks about 11th leading cause of death and 15th leading cause of morbidity, accounting for about 2.2% of deaths and 1.5% of disability-adjusted life years worldwide in 2016.[2] CLD caused 1.32 million deaths in 2017, approximately two-thirds among men and one-third among women.[3]

W.H.O. Indicators

In 1985, an expert group from the World Health Organization (WHO) held a conference meeting in Nairobi, Kenya to discuss the Rationality of Medication Use and Prescribing worldwide.[3] "Rational Drug Use (RDU) is a systemic process in which patients will receive

an appropriate medication to their clinical needs, in doses that meet their requirements for an adequate period, at the lowest cost to them and their community".[4]

The WHO has established three core elements to improve the rational use of drugs worldwide including

1. Prescribing indicators

2. Patient care indicators

3. Healthcare facility-specific indicators.[3]

W.H.O. Prescribing Indicators

There is a growing body of evidence suggesting that using the WHO drug use indicators has become an essential assessment tool to assess the rational drug use pattern in many countries, especially developing countries.[3]

As a result, WHO developed drug (medication) use indicators to ensure and promote rational drug use and to evaluate drug prescribing patterns, including prescribing indicators to evaluate medication-related services provided to the population.[5]

The prescription indicators in practice measure healthcare providers' performances in several key dimensions related to the appropriate use of the drug. These indicators are based on the practices observed in a sample of clinical encounters taking place at outpatient health facilities for the treatment of acute or chronic diseases.[6]

The formula adopted from the WHO's manual for prescribing Indicators assessment

1. An Average number of drugs per encounter = Total number of Drugs prescribed/Total number of encounters sampled. [Indicator (I)-1]

2. Percentage of drugs prescribed by generic name = (Number of drugs prescribed by generic name/Total Number of drugs prescribed) x100. [Indicator (I)-2]

3. Percentage of encounters with an antibiotic prescribed = (Number of patient encounters with an antibiotic/ Total Number of encounters sampled) x100. [Indicator (I)-3]

4. Percentage of encounters with an injection prescribed = (Number of patient encounters with an injection Prescribed/Total number of encounters sampled) x100. [Indicator (I)-4]

5. Percentage of drugs prescribed from Essential Drugs List (EDL) / formulary = (Number of drugs prescribed from essential drugs list/ Total number of prescribed drugs) x100. [Indicator (I)-5] [(III)]

Role of Clinical Pharmacist: Clinical pharmacists can play a very important role in healthcare management by rationalizing and optimizing drug therapy to achieve a better quality of care. In collaboration with the physician, the clinical pharmacist's interventions help to resolve the medication errors and hospitalization of the patient. Distribution of guidelines, running workshops, and seminars on rational drug use to the prescribers can lead to significant improvement in prescribing patterns. By providing rational therapy, clinical pharmacists reduce the socioeconomic burden to the patient and healthcare system.

AIM AND OBJECTIVES

To assess the drug use pattern in Alcoholic Liver Disease using W.H.O. core prescribing indicators.

STUDY CRITERIA: The study was carried out by considering the following inclusion and exclusion criteria.

Inclusion criteria: An out-patient who is willing to participate in the study and who is diagnosed with ALD and comorbidities more than the age of 18 years irrespective of gender was included.

Exclusion criteria: An out-patients who are not willing to participate in the study, below 18 years of age, In-patients, and Special populations such as pregnancy and psychiatry were excluded.

METHODOLOGY: The study was carried out in the Department of General Medicine, Vijayanagara Institute of Medical Sciences (VIMS), Ballari District, Karnataka. For a period of Six Months with a sample size of 150 patients, obtained ethical clearance (TVMCP/IEC/V PD/2021-22/04). Written informed consent was taken by the patients who were included in the study**.** Data was collected from the patient profile document.

The medical history consisting of patient medical records will be reviewed. Data had been recorded as patient demographic characteristics, clinical status, type of complication, and assessed the prescribing pattern of drugs by W.H.O. core prescribing indicators. The recorded data were analyzed statistically.

RESULTS

A total number of 150 subjects were included during the study period.

The demographic details have been described in the following figures:

Such as out of 150 subjects, 146 (97%) were male and 4 (3%) were female subjects (Figure 1).

Among these, the maximum number of patients was between 38 and 48 years (n=64), followed by 28 to 38 years (n=40) (Figure 2).
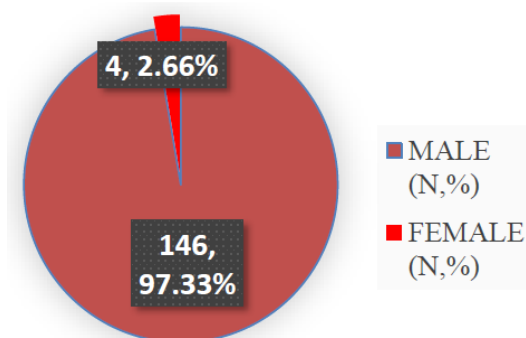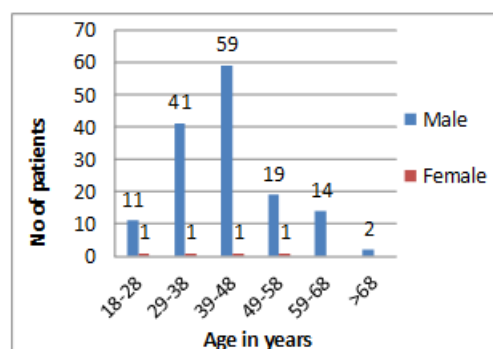

Figure 1: Gender-wise distribution.

Figure 2: Distribution of Patients according to Age.

Out of 150 alcoholic patients, we observed that 66 patients were Smoker and 84 patients were Non-Smoker (i.e., purely alcoholic) (Figure 3).

Among 150 patients, the maximum number of patients were between 10 to 15 years followed by 5 to 10 years duration of alcoholism in terms of years (Figure 4).
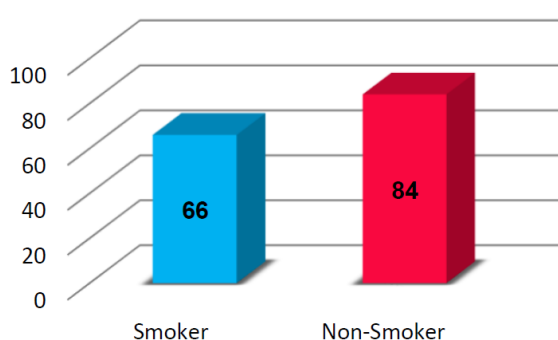

Figure 3: Distribution of Patients Based On Social Habits.

Figure 4: Duration of Alcoholism.

Among 150 ALD patients, various comorbidities present in the study subjects are described in the following, 26 anaemic patients (50.7%), 20 diabetics patients (13.3%) and followed by hypertension(10.7%), renal disease(8%) and others(25.3%) (Figure 5).

Among 150 patients, complications associated with alcoholic liver disease, where we observed Portal Hypertension(40.7%), Ascites(30%), Hepatic Encephalopathy (6.7%), Variceal Bleeding(6.7%), Hepato-Renal Syndrome(2.7%) (Figure 6).
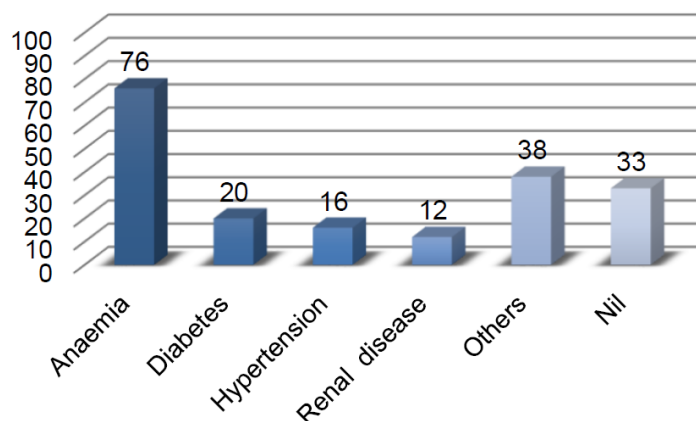

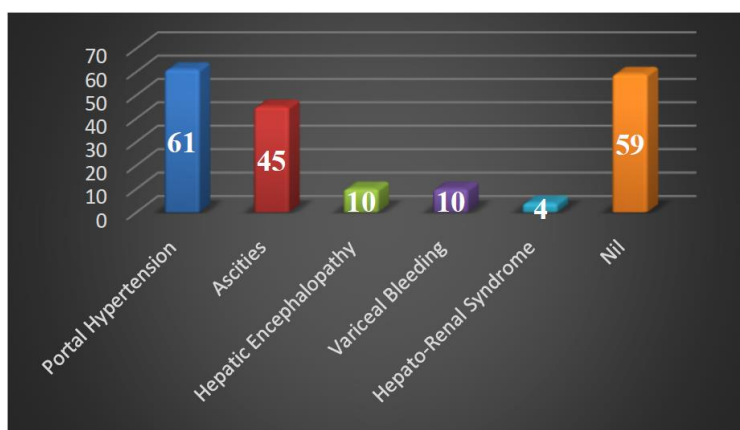**Figure 5: Alcoholic liver disease (ALD) associated with co-morbidities.**

Figure 6: Complications associated with ALD.

W.H.O. prescribing indicators were calculated according to the formula described by W.H.O.

1. Among the 150 prescriptions, the total number of drugs prescribed was about 649 drugs. The average number of drugs per encounter was found to be 4.32.

2. The Percentage of drugs prescribed by generic names was about 53% that is, out of 649 drugs 345 drugs were prescribed by generic names.

3. The Percentage of encounters with an injection prescribed was about 15%, indicating the use of injections.

4. The Percentage of encounters with an antibiotic prescribed was about 19.26%.

5. Out of the total of 649 drugs, 390 drugs(54%) were found to be prescribed from the essential list of medicines (NLEM-2015) (Figure 7).

Out of 150 prescriptions, Less than or equal to 3 were prescribed for 19 patients (12.63%), 4 drugs were prescribed for 72 patients (48%),5 drugs were prescribed for 48 patients (32%),6 drugs were prescribed for 11 patients (7.3%) which will indicate the polypharmacy burden (Figure 8).
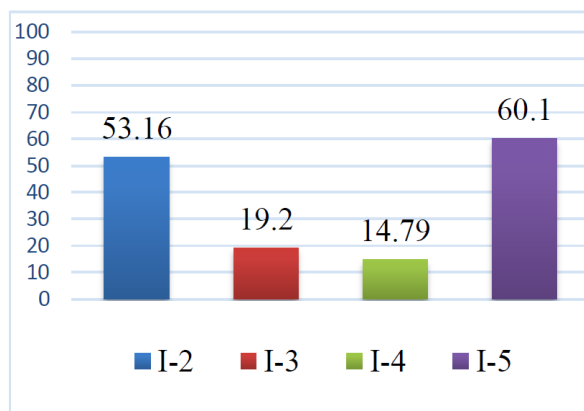

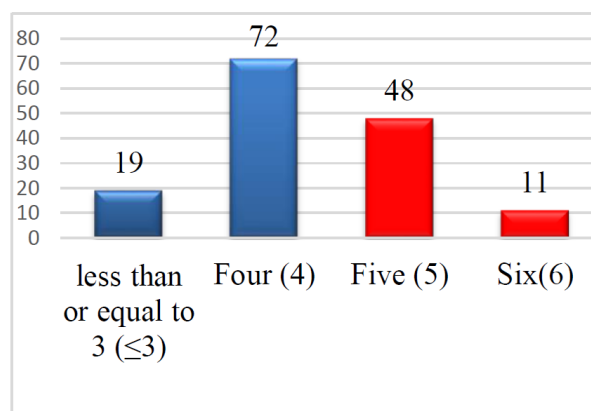**Figure 7: Prescribing Trends.**

Figure 8: Indicating Degree of Polypharmacy.

The Percentage of drugs prescribed by generic names was about 53% that is, where out of 649 drugs 345 drugs were prescribed by generic names (Figure 9).

Distribution of Antibiotics in 150 prescriptions was found to be Rifaximin was prescribed for 84 patients, Ceftriaxone was prescribed for 15 patients, Metronidazole was prescribed for 9 patients, Amoxicillin + Clavulanic acid was prescribed for 4 patients, Cefixime was prescribed for 2 patients, Piperacillin + tazobactam was prescribed for 1 patient, others like albendazole, azithromycin, meropenem were prescribed for 10 patients (Figure 10).
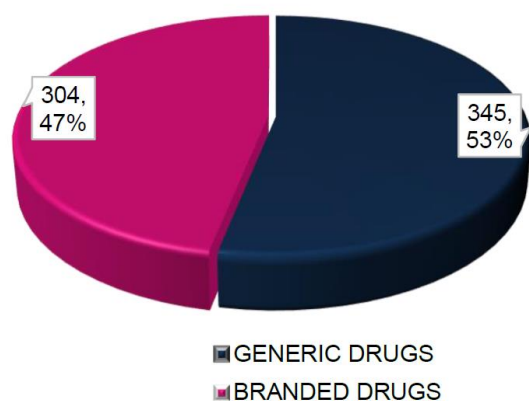

Fig. 9: Distribution of Generic and Branded drugs.
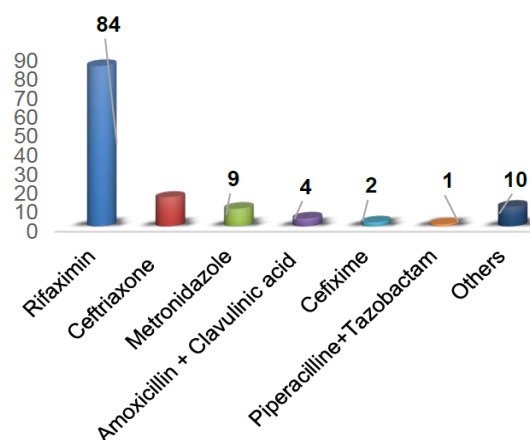

Fig.10: Distribution of Antibiotics.

Distribution of drugs based on the route of administration where most drugs were prescribed oral route such as ALD specific related 162(24.96%) followed by Antibiotics 106(16.33%), diuretics 60 (9.24%), vitamin supplements 57(8.78%), anti-ulcer agents 47(7.24%), anti-emetics 21(3.24%), and others 105(16.18%) which includes steroids, analgesics.

Drugs prescribed in the parenteral route such as Antibiotics 19(2.93%), diuretics 07 (1.08%), vitamin supplements 38(5.85%), anti-ulcer agents 07(1.08%), anti-emetics 2(0.31%), and others 23(3.54%) which includes steroids, analgesics (Figure 11).
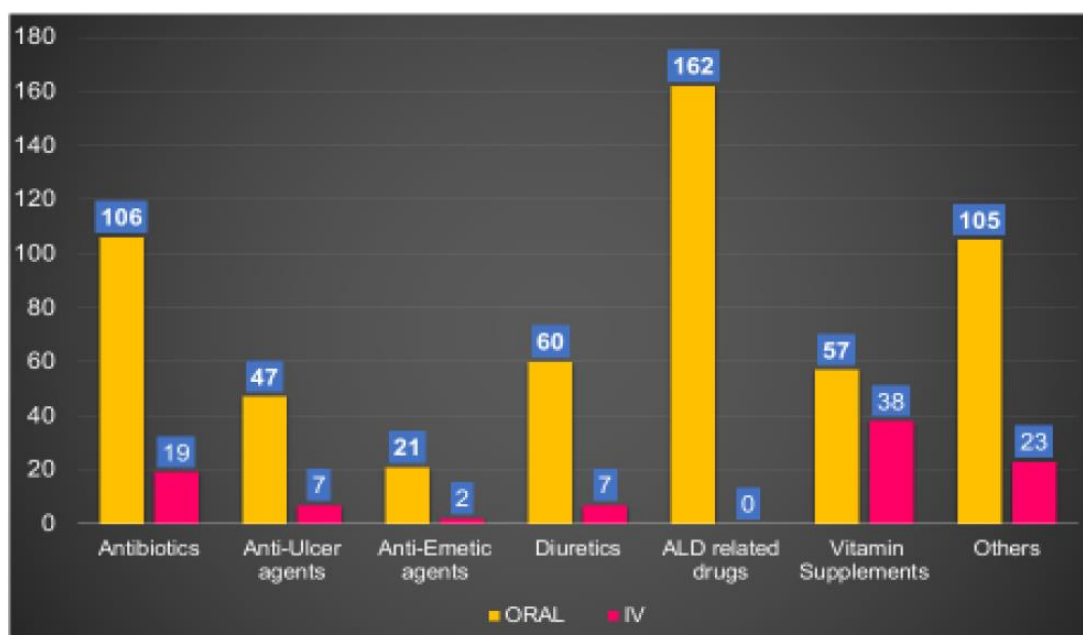

Figure 11: Drug category distribution based on Route of Administration(ROA).

DISCUSSION

Prescription auditing is an important tool for a quality assessment concerning the rational use of drugs in hospitals. The W.H.O. core indicators of prescribing practices measure the performance of healthcare providers in key dimensions related to the appropriate use of drugs.[7]

A total of 150 patients were included in the study among the total study population 146(97.33%) were male and 4 (2.66%) were female patients. The female population is negligibly low concerning ALD. This is attributed to both increased frequency and quantity of alcohol consumption among the male population in the Indian scenario. Also, there are other reasons for decreased alcohol intake in females such as the ADH, the primary enzyme involved in the metabolism of alcohol is up to 40% less active in women than men, women

have a higher percentage of fat than men and thus have less water to dilute alcohol, body size of women are smaller on average than men. These data is resembling Vinayak S.Jamdade et al.

In the present study, 39.99% of patients were aged between 39-48 followed by 27.99% and 13.32% of patients aged between 29-38 and 49-58 years respectively. It may be due to increased alcohol consumption will be more in 39-48 years of age group, because of their stressful life, urban environmental factors, and socio-economic factors, which is similar to Farrah Bilal et al.

In the present study, a total of 150 patients were alcoholics in which we observed that 66 patients(44%) were smokers and 84 patients(56%) were non-smokers.

Table 1: Comparison of prescribing indicators between W.H.O. standard values with other studies.

Prescribing Indicators	I 1	I 2	I 3	I 4	I 5
W.H.O. Standard Value	1.6-2.0	100%	20-26.8%	13.4-24.1%	100%
Vinayak S. Jamadae et al,	7.1	37.77%	22.22%	42.22%	55.55%
Farrah Bilal et al.,	6.2	19.8%	99.3%	97%	100%
Poornima et al.,	5.0	60.16%	--	65.45%	---
Current Study	4.33	53.16%	19.26%	14.79%	60.1%

- Among the 150 prescriptions, the total number of drugs prescribed was 649 drugs. The average number of drugs per encounter was found to be 4.32 which is more than the optimal range(1.6-2), which implies a reflection of polypharmacy. These findings were similar to Poornima et al., study.

- The percentage of drugs prescribed by generic name was about 53.16% i.e., out of 649 drugs, 345 were prescribed by generic name which is found to be much lesser than standard (100%) and can be improved by the motivation of the practitioners. These findings were similar to Vinayak S. Jamadae et al., and Farrah Bilal et al.,

- The percentage of encounters with an antibiotic prescribed was about 19.26% which was found to be within the standard (20-26.8%). These findings were less compared to Vinayak S. Jamadae et al., Farrah Bilal et al., study.

- The percentage of encounters with injections prescribed was about 14.79% which was found to be within the standard(13.4-24.1%). These findings were found to be lesser compared to Vinayak S. Jamadae et al., Farrah Bilal et al., and Poornima et al., study.

- Out of a total of 649 drugs, 390 drugs (60.1%) were found to be prescribed from the Essential List of Medicines(NLEM-2015) which was found to be lesser than the standard(100%). These findings were similar to Vinayak S. Jamadae et al., study.

CONCLUSION

Alcoholic liver disease(ALD) is a serious consequence of drinking alcohol and alcohol dependency is one of the more serious public health issues in the world. It not only affects health but also is a socio-economic burden. Rational Drug Use (RDU) is a systemic process in which patients will receive appropriate medication for their clinical needs, in doses that meet their requirements for an adequate period, at an affordable cost to them and their community.

Our study suggests that there is a need for the conduct of seminars, workshops, and regular training programs to get the values of core prescribing indicators within standard values led by the W.H.O. to ensure rational drug use. There is a need for standard treatment guidelines, availability of essential drug lists, and drug information centers. There is a need to increase the involvement of clinical pharmacists in clinical rounds which promotes RDU and hospital policies.

STRENGTH

These W.H.O. prescribing indicators are highly useful in outpatient and help to formulate the formulary, and policies that help in providing rational therapy.

LIMITATION

Difficulty in gathering data regarding the quantity and type of alcohol consumption by the patients.

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CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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