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Prescription Pattern Analysis in Patients of Alcohol Use Disorder coming to the Psychiatry OPD of a Tertiary Care Hospital in Mumbai district of Maharashtra, India: A Single Centre, Cross Sectional, Observational Study

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Abstract

Alcohol is the most common psychoactive substance used by Indians. The prevalence of alcohol dependence in India is estimated to be 2.7%. In Maharashtra, the prevalence of Alcohol Use Disorders (AUD) is about 4.9%. Prescription pattern monitoring studies are a tool for assessing the prescribing, dispensing, and distribution of medicines. They promote the appropriate use of drugs and reduction of their misuse. With changing guidelines and the availability of newer drugs, it is the need of time to monitor the prescriptions. So, this study was done from October 2019 to January 2021 in a tertiary care teaching institute in western India on 100 patients, which focuses on analyzing the prescribing pattern of drugs in AUD patients. Along with this, potential drug interactions were checked using the Medscape drug interaction checker. A comparison of prescriptions with 2018 APA guidelines was also done. An average 4.77 drugs were prescribed per patient per encounter. 65% of patients were prescribed anti-craving drugs as oral tablets. Only 11% of them were listed in the NLEM, but none were in the hospital drug formulary. The maximum prescribed drugs of other groups were Vitamins (25.7%), Benzodiazepines (22.3%) and Antipsychotics (20.6%). 53.3% of these drugs were from hospital formulary. Potential drug-drug interactions were found in 76%. Adherence to 2018 APA guidelines was present in 89% of cases. This study would provide insight into the trends of drug utilization and feedback to prescribers to create awareness about the rational use of drugs. The evaluation of potential drug interactions can help in solving the problem of polypharmacy.

Keywords: Alcohol dependence, WHO core prescribing indicators, Drug-drug interactions

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Introduction

Alcohol is the most common psychoactive substance used by Indians, followed by Cannabis and Opioids. In India, about 14.6% of the population (between 10 and 75year of age) uses alcohol and 19% of current users of alcohol consume it in a dependent pattern. The prevalence of dependent pattern of alcohol use in India is estimated to be 2.7%. In the state of Maharashtra, the prevalence of alcohol use disorders is about 4.9%[1]. DSM–IV described two distinct disorders, alcohol abuse and alcohol dependence, with specific criteria for each. As per DSM–V (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition), the two DSM–IV disorders- alcohol abuse and alcohol dependence, are integrated into a single disorder called Alcohol Use Disorder (AUD)[2].

The misuse of alcohol is one of the leading causes of preventable death, illness, and injury in many societies throughout the world. Pharmacotherapy along with behavioural therapy plays an important role in preventing alcohol addiction. Advances in neurobiology and associated neurotransmitter systems in development of AUD are also the potential targets for pharmacological approach[3]. Prescription pattern monitoring studies (PPMS) are a tool for assessing the prescribing, dispensing and distribution of medicines. They promote appropriate use of monitored drugs and reduction of their abuse or misuse[4]. These studies guide and support prescribers, dispensers, and general public on appropriate use of drugs, develop working relationship with other key organizations to achieve a rational use of drugs. They explain the extent and profile of drug use, trends, quality of drugs, and compliance with regional, state, or national guidelines. There is increasing importance of PPMS because of a boost in marketing of new drugs, variations in pattern of prescribing and consumption of drugs, growing concern about delayed adverse effects, cost of drugs and volume of prescription[3,4].

The core prescribing indicators of drug use recommended by WHO are calculated from the prescriptions. Prescribing indicators measure general prescribing tendencies within a given setting, independent of specific diagnoses[5]. With the changing guidelines and availability of newer drugs in AUD patients, it is the need of time to monitor the prescriptions[6]. Very few studies have been conducted in the past regarding PPMS of AUD, however no such recent study has been done in our institute. So, this study is done which focuses on analysing the prescribing pattern of drugs in patients of alcohol use disorders. Along with this, potential drug interactions are also checked using Medscape drug interaction checker.

Methods

This study was conducted from October 2019 - January 2021 in a tertiary care teaching institute in Mumbai district of Maharashtra, India. Its protocol was approved by the Institutional Ethics Committee prior to commencement of the study. As the prevalence of 4.9% of AUD in Maharashtra, the minimum sample size calculated was 72. So, 100 patients were taken as study population. The inclusion criteria were prescriptions of patients of either sex, 18-60 years of age coming to the Psychiatry OPD and diagnosed as a case of AUD. Pregnant alcoholic patients and those not interested in participating in the study were excluded. Patients were given patient information sheet and their informed consent was taken. The demographic profile, diagnosis, number, and type of anti-craving drugs and other classes of drugs along with their dose, frequency, duration was captured on a structured case record form and analysed.

The prescription pattern was then studied, as per WHO core prescribing indicators-

a. Average no. of drugs prescribed per encounter
b. Percentage of anti-craving drugs prescribed
c. Percentage of other classes of drugs prescribed
d. Percentage of different dosage forms prescribed
e. Percentage of drugs prescribed by generic name
f. Percentage of drugs prescribed by brand name
g. Percentage of drugs prescribed from National List of Essential Medicines (NLEM)
h. Percentage of drugs prescribed from available Hospital Drug Formulary

Potential drug interactions were checked using Medscape Drug Interaction checker. Comparison of prescriptions with 2018 APA (American Psychiatric Association) Guidelines for treatment of AUD was also done.

Results and Discussion

Total 100 prescriptions were analysed. The demographic profile shows that greater number of male (93%) suffered from AUD as compared to female (7%). Male preponderance has also been observed in other previous Indian studies[7-10]. This may be due to the sociocultural aspects of the country, where almost exclusively males are involved in alcohol intake[8]. Out of 100 patients enrolled, majority(32%) belonged to age group 31-40 years and the least number of patients were in the age group <21 years (Figure 1), mean age being 36.08 years. This coincides with the data from other similar Indian studies[7,9,11]. In a study done by Vijayan M et al, majority belonged to the age group 51–60 years, followed by 41–50 years[12].

Prescription Data

Average number of drugs prescribed per encounter

Average 4.77 drugs were prescribed per patient per encounter, which included drugs for treatment of AUD along with drugs for other associated conditions. This measures the degree of polypharmacy. According to WHO, it should be monitored to prevent over prescribing and to avoid the risk of drug-drug interactions. Therefore, it is advisable to keep the number of drugs as less as possible.

Percentage of anti-craving drugs prescribed

65% patients(n=100) were prescribed anti-craving drugs.

Prescribing pattern of anti-craving drugs

Out of 65 patients, 53(81.5%) were prescribed Acamprosate, 11(16.9%) were prescribed Baclofen and 1(1.5%) was prescribed Naltrexone. In a study done by Dube et al similar results were seen[8]. The anti-craving drugs were in tablet form. The results are in accordance with other similar Indian studies[13,14]. This pattern of prescribing anti-craving drugs is approved by the US FDA. Acamprosate is effective for both maintaining abstinence and for reducing heavy drinking days[15]. Acamprosate and Naltrexone have the best evidence for improving alcohol consumption outcomes for such type of patients[16]. Baclofen appears to delay return to drinking and help sustain abstinence, particularly in individuals who at baseline drink very heavily[17].

Percentage of other classes of drugs prescribed

A total of 412 other drugs were prescribed along with anti-craving drugs. They were prescribed for other comorbid conditions, substance abuse and psychiatric disorders.

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Classes of drugs prescribed

The different classes of drugs prescribed are shown in Figure 2. The maximum prescribed drugs were Vitamins, prescribed 107(25.7%) times, followed by Benzodiazepines, 93(22.3%) and Antipsychotics 86(20.6%) times. Our results are in line with a previous study done by Dube U et a[8]. As nutritional deficiency is common in patients of AUD, Vitamins were found to be the most prescribed drugs.

Prescribing patterns of Benzodiazepines

For decreasing the withdrawal symptoms, Benzodiazepines (BZDs) were prescribed. Among the BZDs, Lorazepam (83%) was the most prescribed drug, followed by Clonazepam (9%), Clobazam (6%) and Alprazolam (2%). Similar findings were also seen in a study done by Dube et al[8]. Benzodiazepines are effective because they stimulate the inhibitory GABA-signaling pathways. They suppress alcohol withdrawal symptoms and shorten the course of withdrawal, and they are the only agents that have been shown to prevent withdrawal associated seizures, delirium tremens, and death in patients undergoing alcohol withdrawal. Although many different benzodiazepines have been shown to be effective, lorazepam, chlordiazepoxide, oxazepam, and diazepam are the benzodiazepines most commonly used to treat alcohol withdrawal[18].

AUD with other substances of abuse

Out of 100 patients, 48% had other substance abuse along with AUD. Among these 48 patients, Nicotine was the most common substance of abuse and Amphetamine was the least common one. Among these 48 patients, 34(70.83%) had Nicotine, 7(14.58%) had Cannabis, 5(10.42%) had Opioid and 2(4.17%) had Amphetamine use disorder (Figure 3).

In a study done by Connor JP et al, it was found that at least half of the patients had nicotine use disorder[10]. In a similar study done by Arias F et al, cocaine, cannabis and opiate were the most abused substances along with alcohol[19]. It has been found that polysubstance abuse has higher risk of comorbid psychopathology, health problems and deficits in cognitive function[20]. Both alcohol and nicotine are highly comorbid and there is a strong correlation between alcohol and nicotine dependence. The patients with AUD are three times more likely to abuse nicotine than the general population[21]. Concurrent use of alcohol and nicotine may exacerbate the health effects of either substance alone, with increased risk for cancer of mouth, throat and liver[22,23]. Additionally, for alcohol-dependent individuals, it also increases the risk of nicotine-related diseases (heart and lung disease) and death from complications[24].

AUD with psychiatric conditions

Often individuals with mental health disorders use substances to reduce stress or relieve symptoms. Among the 100 patients enrolled for the study, 50% had AUD with psychiatric comorbidities. Personality disorder was the most common psychiatric comorbidity, affecting 24(48%) patients, mood disorders in 20(40%), psychosis in 4(8%) and substance induced behavioural disorders in 2(4%) patients. In a similar study done by Kessler RC et al, it was found that major depressive disorder was most common with AUD[25].

The prevalence of most mood, anxiety, substance, and thought disorders is higher in people with AUD than in the general population[26]. Given the high co-occurrence between AUD and mental health conditions, and the increased morbidity associated with the presence of co-occurring disorders, it is important to identify the co-occurring disorders and to address both disorders in treatment to improve treatment outcome. Treatment that addresses both disorders concurrently with the same provider is called integrated treatment[27].

Although pharmacological and psychosocial treatments for AUD and psychiatric disorders can be integrated to help these patients, relatively few clinical studies have tested these types of therapy. An approach to address this issue is seen in a study[28]. In our study also, other co-existent affective disorders were treated with antipsychotics and antidepressants.

Percentage of different dosage forms prescribed

All anti-craving drugs were prescribed in oral tablet form. This WHO indicator provides us the information regarding usage of various drug formulations.

Percentage of formulations of other classes of drugs prescribed

Out of the 412 other class of drugs prescribed, 356(86.5%) were in tablet form, 54(13.1%) injectables, 1(0.2%) capsule and 1(0.2%) syrup. This information regarding drug formulations can be considered as a basis of cost calculation and its comparison among various prescriptions and, subsequently the pharmacoeconomic burden on the patient.

Percentage of drugs prescribed by brand & generic names

Out of 65 anti-craving drugs prescribed, 56(86%) were prescribed by brand name and 9(14%) prescribed by generic name. Out of 412 other drugs prescribed, 206(50%) were prescribed by generic name and 206(50%) prescribed by brand name. Prescribing drugs by generic names makes the treatment cost-effective and avoids prescription errors[29]. Hence, we should encourage it as much as possible. This can be achieved by educational intervention methods and strict compliance with WHO drug policies. In a study done by Kolasani BP et al, percentage of drugs prescribed by generic name were 42.1% and brand name were 57.9%[7].

Presence of drugs in NLEM/ Hospital Drug Formulary

Essential medicines, as defined by WHO are those drugs that satisfy the health care needs of most of the population. They should, therefore, always be available, in adequate amounts and in the appropriate dosage forms, at a price the community can afford[29]. In our study, the percentage of drugs prescribed from NLEM, India was 56.1% which is higher than a study where it was 31.7%[30]. WHO recommends the drugs prescribed from NLEM to be 100%. So, there is a need to adhere to the NLEM while prescribing, as it does not only promote rational use of medicines, but also promotes prescription by generic names. Out of total 65 anti-craving drugs, only 11% were listed in the NLEM, but no drugs in Hospital Drug Formulary. Availability of drugs in hospital formulary is helpful for the prescribers to prescribe cost-effective drugs, which reduce financial burden to the patients. In our study, 53.3% drugs prescribed were from hospital formulary, which was little lesser compared to a similar study[8], where 60.9% drugs were from hospital formulary. By giving this feedback to the hospital administration, it will help in the procurement and utilization of drugs.

Potential drug-drug interactions

Out of 100 prescriptions, potential drug-drug interactions were found in 76%, of which 59% were minor. They were checked through Medscape drug interaction checker[31]. They ranged from minor, moderate, and major interactions, as follows

1. Major/Serious: Highly clinically significant. Avoid combinations; the risk of the interaction outweighs the benefit. Effects are potentially life threatening or capable of causing permanent damage.
2. Moderate: Moderately clinically significant. Use it only under special circumstances/ close monitoring required. Effects may cause deterioration in patients'

clinical status and additional treatment or extension of hospital stay.

3. Minor/ Mild: Minimally clinically significant. Interaction is unlikely to be clinically relevant. Effects are usually mild.

Polypharmacy is one of the major reasons for drug interaction. An idea regarding the potential drug interactions can help the prescribing physician to take care of untoward consequences. As this was a cross sectional, single encounter study, actual drug-drug interactions were not assessed.

Comparison of prescriptions with 2018 APA Guidelines for treatment of AUD

The observed patterns of drug use can be compared with the current recommendations and guidelines for the treatment of a certain disease. Hypotheses can then be generated to determine whether discrepancies represent less than optimal practice, whether pedagogic interventions (education) are required or whether the guidelines should be reviewed in the light of actual practice[4]. In this study, out of 100 prescriptions, adherence to 2018 APA, AUD guidelines was found in 89% cases. APA recommends (1B) that Naltrexone or Acamprosate be offered to patients with moderate to severe alcohol use disorder who have a goal of reducing alcohol consumption or achieving abstinence[6]. Acamprosate and Naltrexone were actually the anti-craving drugs prescribed, as per the guidelines. 11% patients were also prescribed Baclofen 30mg tablet. The frequency, dosage, and duration of drug therapy are the three important parameters, and if not clearly recorded, can result in indiscriminate, injudicious use of drugs and therapeutic failure. These parameters were in accordance with the guidelines.

Conclusion

This study was done to provide an insight into the trends of drug utilization and provide feedback to prescribers to create an awareness about rational use of drugs. The use of anti-craving drugs along with multivitamins and BZDs is the mainstay of treatment for these alcohol dependent patients. Anti-craving agents like Baclofen, Acamprosate and Naltrexone were prescribed in our study. AUD is seen to co-exist with other co-morbidities like psychosis, anxiety, and depression. Potential drug interactions were found in majority of the prescriptions. Educating the prescribing physicians about the potential drug interactions can help in solving the problem of polypharmacy.

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Conflict of Interest

None declared.

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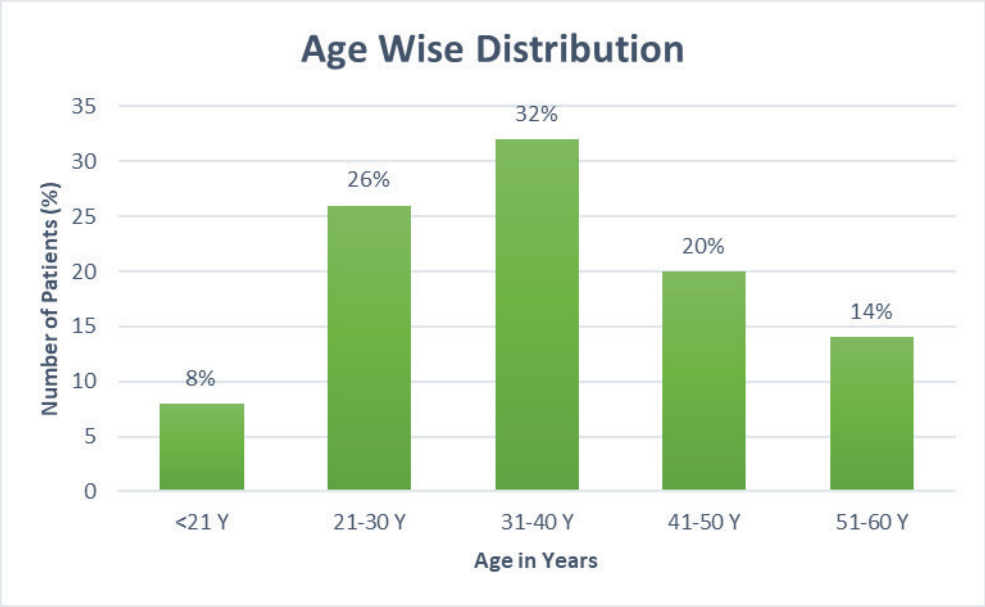

Figure 1. Age wise distribution of patients treated for AUD

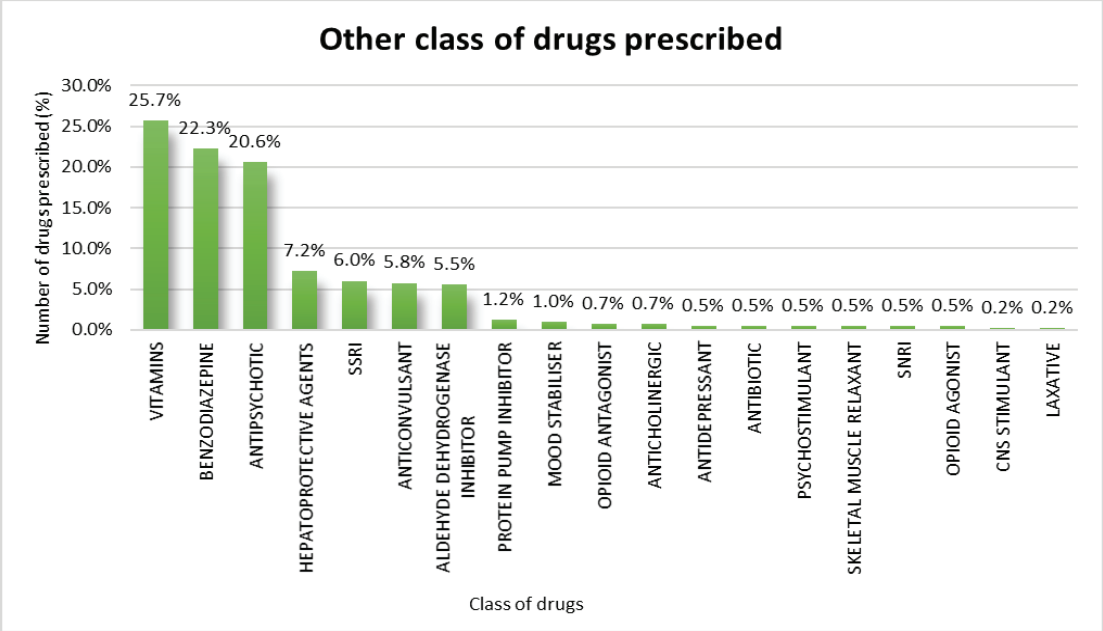

Figure 2. Other classes of drugs prescribed

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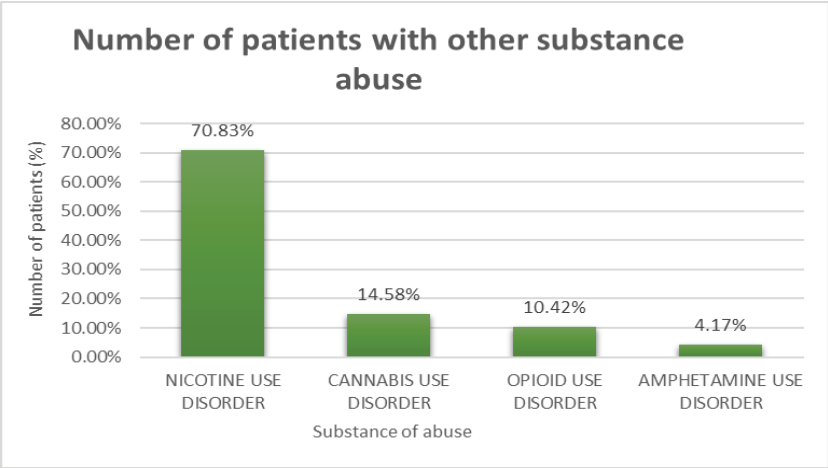

Figure 3. Number of patients with other substance abuse (n = 48)