

Original Research Article

A study on patients with alcohol dependence syndrome on tablet baclofen in a tertiary care hospital

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ABSTRACT

Background: Many clinical trials indicate that baclofen, a gamma-aminobutyric acid agonist has efficacy for alcohol dependence to reduce the cravings of alcohol and it may also have certain common or rare ADRs. Aim was to evaluate tablet baclofen's adverse effects and sociodemographic profile in the treatment of ADS.

Methods: This study was carried out in MVJ Medical College and Research Hospital Bangalore, India. The socio-demographic questionnaire and NADRP was administered to 100 patients who was on tablet baclofen with alcohol dependence syndrome that were diagnosed according to the ICD-10 diagnostic criteria, as well as 100 subject all of whom gave their informed consent. The data were analysed using Microsoft excel.

Results: As a result, this present data analysis revealing that alcohol addiction was more prevalent in the 36 to 50 age group, men among women. Primary school students were more addicted to alcohol, with non-professionals, rural areas, and nuclear families having higher addiction rates. Most alcohol dependence subjects have a tobacco history and comorbid mental and behavioral disorders. NADRP scales indicate no severe adverse drug reactions in alcohol dependence syndrome patients.

Conclusions: Results showed that ADS is more prevalent in the adults, married patients lack of education, occupation, and family size also contributed to addiction. Rural areas had higher alcohol addictions than urban ones, and nuclear families were more likely to abuse drugs. The study concluded that tab. baclofen is a rational medicine for treating ADS.

Keywords: Adverse effects, Alcohol dependence syndrome, Psychiatry, Sociodemographic profile, Tablet baclofen

INTRODUCTION

Alcohol dependence is a major problem in India, based on twenty-one studies conducted in different states of India included 73997 community-based respondents, which estimated the overall prevalence of AUDS as 12.5%.¹ Alcohol dependence, sometimes referred to as alcohol use disorder (AUD), is a chronic and crippling illness marked by obsessive and unchecked alcohol consumption that causes serious physical, psychological, and social problems. There are few alternatives for alcohol dependence treatment, despite the condition's frequency

and effects, and there is an urgent need for efficient therapies to help those who are dealing with the disorder.²

Baclofen is used to relax skeletal muscles. Baclofen was initially developed in 1962 to treat epilepsy, but this use did not prove successful; instead, it was shown to lessen stiffness in some individuals. In order to treat spasticity, baclofen was once again introduced in 1971. The FDA later approved baclofen in 1977. Including multiple sclerosis and traumatic brain injury, baclofen is used to treat severe muscle spasms that have cerebral or spinal cord origins. Alcohol dependence and withdrawal were

examined with baclofen, but there is insufficient and conflicting evidence to support its therapeutic usefulness in treating these symptoms.²⁻⁴ They may also be used for following conditions such as muscle spasm due to sprains, torticollis, fibrositis, tetanus, myositis.⁵

Although it has not been successful in treating acute alcohol withdrawal, the GABA_B receptor agonist baclofen, which was created in the 1960s and has been approved as a treatment for muscle spasticity since the 1970s, has showed encouraging results in the treatment of alcohol dependency since 1993.^{6,7} After several failures with various treatments, Ameisen found that baclofen may control alcohol cravings for up to 270 mg per day.⁸

Mechanism of action

Baclofen is a GABA_B agonist which activates GABA_B receptors depressing the monosynaptic and polysynaptic reflexes in the spinal cord thereby acting as a muscle relaxant.

Baclofen is stressed as a promising and distinctive drug for use in the treatment of alcohol reliance due to the lowering goods it has on alcohol appetite and consumption during AWS. This drug is particularly interesting because to its effectiveness in treating two important symptoms of the condition, videlicet AWS and abstinence conservation. This particular property of baclofen is anticipated to lead to important simplified pharmacotherapy for drunkenness and advanced treatment compliance.¹⁴

Low tablets of baclofen that are also supplied with alcohol have been proven to be well permitted, still inordinate boluses of baclofen taken by people with alcohol issues might have serious side goods similar storms.¹⁶ This finding is in line with findings from a public study of the general crowd, which showed that alcohol dependence was more common in men (10.5) than in women (3.6).¹⁴ Women showed simply a trend toward an advanced threat when it came to the connections between gender and anxiety, depression, or both (as determined by the PHQ-4; $p=0.07$).

Studies involving medical residents have shown disagreeing results, despite the general population's observation that women had an advanced prevalence of both anxiety and depression.^{2,16,19} All work-related variables, as well as their connections with internal health issues among medical residents, were shown to be statistically significant.¹⁷ Baclofen can also produce fall in BP, tachycardia visual and audible daydream (infrequently).⁵ A recent meta-analysis revealed that studies that used lower tablets of baclofen had superior issues to those that used larger boluses. Lower boluses are also linked to a dropped threat of adverse goods.¹⁸

Baclofen was well permitted with only two individualities stopping baclofen because of adverse events. There were no serious adverse events.¹⁹ So as to ascertain the baclofen

side goods in cases with alcohol dependent pattern use of the Naranjo adverse drug response scale.⁸ ICD criteria F10 are used to the case's opinion of advertisements.⁷ Sociodemographic scale is used to determine the state of cases' bio data.

Objectives

This study was done to evaluate tablet baclofen's adverse effects and sociodemographic profile in the treatment of ADS.

METHODS

Study design and participants

This observational study was conducted in Bangalore, India at the MVJ Medical College and Research Hospital. Along with 100 subjects who provided their informed consent, the Naranjo adverse drug reaction probability scale (NADRP) and a sociodemographic questionnaire were given to 100 patients with alcohol dependence syndrome who were taking baclofen tablets and had been diagnosed with the ICD-10 diagnostic criteria. Microsoft Excel was used to analyze the data. The study was carried out from March 2023 to August 2023, a span of six months.

Inclusion criteria

Patients diagnosed with alcohol dependence syndrome, who have been prescribed tablet baclofen as part of the treatment. Age above 18 years.

Exclusion criteria

Patients with severe liver or kidney disease, who were pregnant or breastfeeding and with a history of allergic reactions to baclofen or other medications in the same class.

Data collection tools

Sociodemographic and clinical details form

A questionnaire (10 questions) was administered to assess the general profile of the respondents, including sociodemographic, academic and clinical details.

Naranjo drug adverse reaction probability scale

The NDARP scale was given to study participants who gave their assent. The ADR probability scale consists of ten questions with yes, no, and don't know responses. For every answer, a different point value (-1, 0, +1, +2) is assigned. ADRs are certain if their total score is greater than 9, probably if it is between 5 and 8, and possibly possible if it is between 4 and 5. It is a dubious ADR if the final score is less than zero.

Statistical analysis

For the sociodemographic variables and NDARP scale questionnaires, descriptive data is presented in the form of Mean±SD and percentages. All analysis were conducted using SAS 9.2. Statistical significance was defined as $p < 0.05$.

RESULTS

The study was carried out to evaluate tablet baclofen's adverse effects and sociodemographic profile in the treatment of ADS. Study was conducted among 100 subjects in psychiatric ward of MVJ Medical College and Research Hospital. The results after analysis of data are contained in this chapter. Based on collected data from the patient descriptive analysis was carried out and the results were found. From sociodemographic profile scale, age distribution, 2 were between 18-25 years, 22 were between 26-35 years, 41 were between 36-50 years and 35 were above 50 years. As shown in the Figure 1, alcohol addiction appears to be more prevalent in the 36 to 50 age group. Gender distribution, 38 were female and 62 were male. According to study, men were more addicted to alcohol than women. Distribution based on marital status, 75% were married, 9% were single and 16% were divorced or separated. This revealed that married persons are more likely to be addicted to alcohol and other drugs than the singles, divorced or separated.

Table 1: Descriptive analysis for age, gender, marital status, education, occupation, residency.

Demographic parameters	Mean±SD	% (n=100)
Age (years)	25±17.262	
18-25		2
26-35		22
36-50		41
Above 50		35
Gender	50±16.970	
Male		62
Female		38
Marital status	33.33±36.25	
Single		9
Married		75
Divorce/separated		16
Education	33.33±21.45	
Primary school		58
Secondary school		23
Graduated		19
Occupation	33.33±16.196	
Professional		23
Non professional		52
House wife		25
Residency	50±28.284	
Rural		70
Urban		30

Table 2: Descriptive analysis for alcohol history and comorbidities.

Variable	Mean	Median	SD	SD max.	SD min.	Variance	Range	N	%
Alcohol	25	24	22.31	50	2	498	48	100	
Age (years)									
Below 3									2
4-15									37
16-30									11
Above 30									50
Comorbidity	12.5	3.5	25.03	74	1	626.85	73	100	
MBD									74
SCH and CT									1
DM									2
HTN									7
OA									1
P. SCH									5
BD									1
DP									9

Distribution based on education, 58% of subject study primary school, 23% were secondary school and 19% were graduated. As per the study we found primary school is more addicted to alcohol than the secondary and graduated. Distribution based on occupation, 23% were professional, 52% were nonprofessional and 25% were house wife. It shows non-professional is having more

alcohol and substance abuse (Figure 2). Distribution based on residency, 30 subjects were from urban and 70 were from rural. Rural areas had higher addiction to the alcohol use. Distribution based on family size, 48 subjects were in extended family and 52 subjects were in nuclear family. Nuclear families were addicted to alcohol and other substance abuse. Distribution based on tobacco history, 66% of subjects were consuming tobacco and 34% were

non tobacco. We found that majority of alcohol dependence subjects were also having tobacco history and descriptive analysis data is shown in Table 1. Distribution based on alcohol history, 2 were having below 3 years of alcohol history, 37 were having 4 to 15 years of alcohol history, 50% were having 16 to 30 years of alcohol history and 11% were having above 30 years of alcohol history (Figure 3).

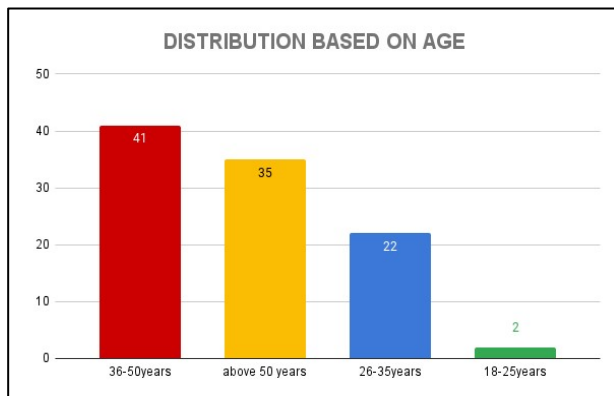


Figure 1: Distribution based on age.

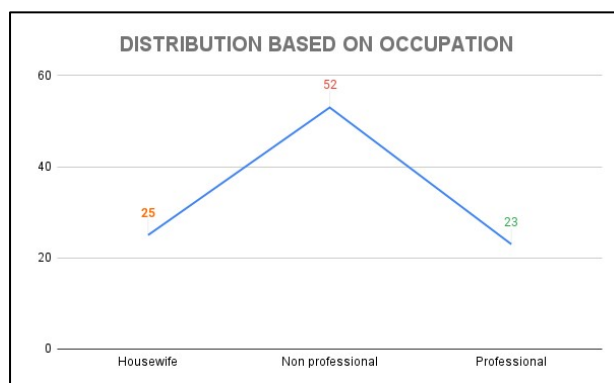


Figure 2: Distribution based on occupation.

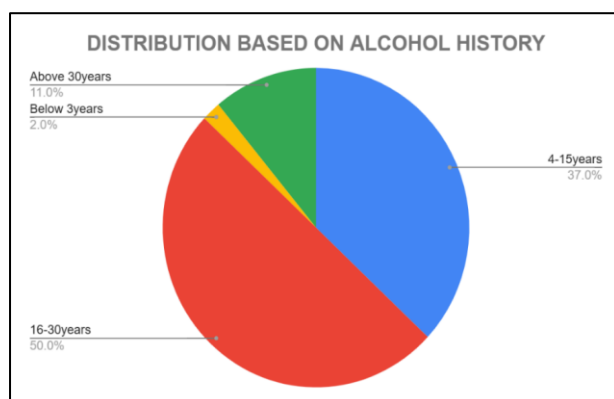


Figure 3: Distribution based on alcohol history.

Distribution based on comorbidity, 74 were having mental and behavioral disorder, 9 were having depression, 7 were having hypertension, 5 were having paranoid

schizophrenia, 1 of them was having bipolar disorder, 1 was having osteoarthritis, 1 was having schizophrenia and catatonia and 2 of them were having diabetes mellitus. Majority with alcohol dependence syndrome were having comorbidity of mental and behavioral disorder (Figure 4) and descriptive analysis data is shown in Table 2.

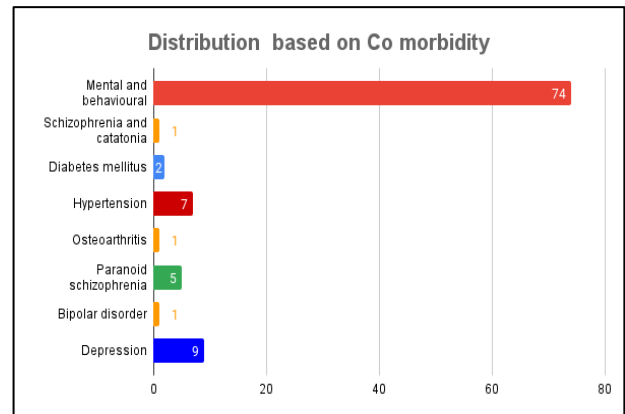


Figure 4: Distribution based on co-morbidity.

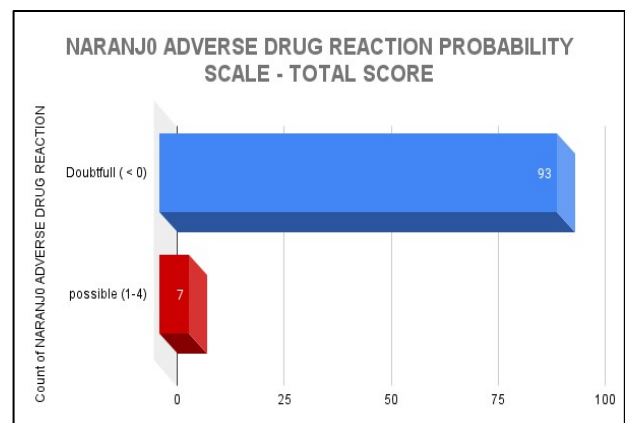


Figure 5: Naranjo adverse drug reaction probability scale.

From NADRP scale, based on the percentage of each questionnaire by 100 subjects the total score shows 7% possible (1-4) ADR and 93% doubtful (≤ 0) ADR can be seen tablet baclofen in the treatment of ADS patients shown in Figure 5 and Table 3.

Table 3: Descriptive analysis for NADRP scale.

Descriptive analysis	Values
Mean	50
Median	50
SD	42.426
SD max	80
SD min	20
Variance	1800
Range	60
N	100

DISCUSSION

A significant issue in India is alcoholism. It is also known as alcohol use complaint; it is a debilitating condition characterized by obsessive and limitless alcohol intake that leads to severe neurological, bodily, and social issues. Acquiring the ability to calm cadaverous muscles, baclofen has also been used for the treatment for alcohol dependence pattern.^{1,5,10} Basing its treatment of alcohol dependence pattern on numerous clinical trials conducted by Bschor et al, baclofen is emphasized as a unique and promising medication.¹⁰ While it does have many benefits, it also has a number of negative drug reactions, including headaches, nausea, fatigue, dizziness, constipation, problems passing urine, and impaired vision.^{6,13} The clinical investigation conducted by Loureira and Pereira-lima established that sociodemographic factors are also accountable for alcohol dependency and other substance abuse.¹⁷ Recent meta-analysis research conducted by Addolorato et al found that baclofen tablets with smaller dosages outperformed those with higher boluses in terms of growth and was approved with no significant side events.¹⁴ This investigation was carried out at the mental unit. This six-month experimental prospective study was conducted in the sanatorium's outpatient department. Three separate questionnaire forms- the sociodemographic scale, the NADRP scale, and the ICD criteria F10 form- were used for our investigation. We gathered each subject's answer to each query by employing this various instrument, which is questionnaires. Garbutt and Kampov-Polevoy found in their clinical research that baclofen adverse effects are less likely at lower dosages.¹⁹ In 19 advertisements, there were no significant side goods. The results of a clinical trial by de Beaurepaire showed that the side effect was inoffensive. At one point, they reported experiencing fatigue, headaches, nausea, dizziness, constipation, edema, and electrical discharges. However, statistical analysis revealed no statistically significant associations between the side effects, either individually or collectively. Based on preliminary data, no significant relationship was found between the presence of an accompanying internal complaint and side effects.¹⁵ This study examined the negative effects of tablets containing baclofen in cases of advertisements as well as the sociodemographic makeup of such cases. We set up that 36-50 times older persons were receiving advertisements compared to people in other age groups in our study by using a sociodemographic scale. Extremely masculine and feminine cases of alcoholism were widely publicized. The married person is more likely to be an alcoholic than the single or divorced person, depending on their respective relationship status. It is established that individuals who are prone to alcoholism and other substance misuse disorders also have a significant issue with low levels of education. We established a primary academy and found that both the secondary and graduated schools had higher rates of alcohol addiction. Using a sociodemographic scale, we configured the study such that individuals 36-50 times older were receiving advertising than people in other age groups. Extremely publicized incidents of alcoholism

included both feminine and masculine individuals. Depending on their individual marital state, married people are more likely to be alcoholics than single or divorced people. Research has demonstrated that there is a substantial correlation between poor educational attainment and the development of alcoholism and other substance abuse disorders. After establishing a primary academy, we discovered that alcohol addiction was more common in both graduated and secondary schools. Our results were consistent with a prior clinical investigation by Pereira-Lima, which explored the association between specific, work-related, and sociodemographic characteristics and mental health in medical residents.¹⁷ We diagnosed the participants using ICD criteria F-10 in order to determine whether or not they had a pattern of alcohol dependence. We determined through our investigation that there are no significant adverse drug reactions (ADRs) associated with the pill baclofen in cases of alcohol dependent patterns.¹⁴

As the study was done with small sample size, the inference of the has limited value and less statistical power. Data collected was only of those who were available and willing to participate at the time of study. The study was generally based on the patient self-reporting factor where accuracy of the data can be compromised. As the patients were having less days of hospital stay, we were able to collect the patient data for short period of time. As the study was conducted, in patient department, it does not give the information on prescription pattern in our patients.

CONCLUSION

To assess the side effects and sociodemographic profile of tab. baclofen in the management of ADS, our study was conducted. It was concluded from the findings that, ADS was more common in the 36 to 50 age range compared to other age ranges. We found that patients who were married had higher alcohol addiction rates than patients who were single, divorced, or legally separated, regardless of their marital status. The study indicated that elementary school students are more hooked to alcohol than secondary students and graduates, which led us to the conclusion that lack of education is a significant problem. It is clear from occupation, location, and family size data that non-professionals abuse alcohol and other drugs more than professionals (non-professionals >> housewives > professionals), that rural areas have higher rates of alcohol addiction than urban areas, and that nuclear families are more likely to engage in substance abuse than extended families. Most of the patients in our study who struggled with alcoholism also had a history of smoking. Most people who experience alcohol dependence syndrome also have co-occurring mental and behavioural issues. Each patient underwent an ICD diagnostic to establish whether they had alcohol dependant syndrome.

The NADRP scale led us to the conclusion that patients taking baclofen pills for alcohol dependency syndrome had doubtful ADRs. When it comes to the treatment of

those with alcohol dependent syndrome, baclofen is a Rational drug.

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