

A PROSPECTIVE OBSERVATIONAL COMPARATIVE STUDY OF BACLOFEN AND LIBRIUM IN ALCOHOL WITHDRAWAL SYNDROME

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ABSTRACT

Objectives: The objective of the study was to evaluate the safety, effectiveness, and anti-craving properties of baclofen and Librium (chlordiazepoxide) in patients with alcohol withdrawal syndrome (AWS).

Methods: This was a prospective observational study including patients with a history of alcohol consumption and diagnosed with AWS. Participants were treated with baclofen and Librium. The Clinical Institute Withdrawal Assessment (CIWA) scale was used to assess the severity of withdrawal symptoms. The effectiveness of baclofen and Librium was evaluated based on symptomatic relief.

Results: Out of 492 patients screened, 367 subjects were attended 3 follow-ups and provided information regarding effectiveness of baclofen, Librium, and improvement of their quality of life. Both baclofen and Librium produced a significant reduction in CIWA-Ar scores. Analysis of individual CIWA-Ar subscales showed that both drugs significantly reduced sweating, tremors, and anxiety. Although Librium showed a faster onset of effect than baclofen, baclofen has greater anti-craving properties for alcohol.

Conclusion: Librium and baclofen both consistently reduced the overall CIWA-Ar scores. Compared to Baclofen, chlordiazepoxide offered faster and more efficient alleviation from the symptoms of alcohol withdrawal. AWS was another condition for which Baclofen demonstrated encouraging results. Baclofen shows comparable efficacy to Librium in the treatment of AWS, suggesting its potential role as an alternative therapy.

Keywords: Alcohol withdrawal syndrome, Baclofen, Librium, Gamma-aminobutyric acid analogue, Clinical institute withdrawal assessment-Ar, Craving.

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INTRODUCTION

In many countries, drinking alcohol is both socially acceptable and legal. It increases levels of high-density lipoprotein, which are linked to a reduced risk of heart disease [1]. Consuming 150 mL (5oz) of red wine daily can help prevent heart disease. However, long-term alcohol consumption can harm liver cells, leading to dysfunction. It can cause liver inflammation, such as alcoholic hepatitis and cirrhosis [2]. In addition, chronic alcohol use leads to the gradual degeneration of the nervous system, damaging neurons [3].

According to the 2018 World Health Organization report, over 3 million people died in 2016 due to the harmful use of alcohol, accounting for 1 in every 20 deaths. More than three-quarters of these fatalities occurred in men. The harmful use of alcohol contributes to over 5% of the global disease burden [4].

Alcohol dependence is a severe form of alcohol use disorder, occurring when an individual experiences withdrawal symptoms after stopping alcohol consumption. This may be triggered by factors such as family pressure, personal motivation, physical illness, or difficulty obtaining alcohol [5]. Many regular drinkers believe that quitting alcohol causes more problems than continuing to drink, which is partially true for those who have developed dependence. These individuals may experience withdrawal symptoms, including autonomic arousal, hallucinations, seizures, and delirium tremens [4].

Alcohol acts as a central nervous system (CNS) depressant, influencing the inhibitory neurotransmitter gamma-aminobutyric acid (GABA).

In a balanced state, excitatory (glutamate) and inhibitory (GABA) neurotransmitters maintain homeostasis. Alcohol enhances GABA's effects, reducing CNS excitability. Over time, this leads to a decrease in the number of GABA receptors (downregulation), resulting in the need for progressively larger doses of alcohol to achieve the same euphoric effect, a phenomenon known as tolerance. Alcohol also functions as an N-methyl-D-aspartate (NMDA) receptor antagonist, lowering CNS excitatory tone. Chronic alcohol use leads to an increase in NMDA receptor numbers (upregulation) and more glutamate production to maintain CNS homeostasis [6].

Baclofen has been used safely for decades as a smooth muscle relaxant. Recent advancements in understanding the pathophysiology of alcohol withdrawal syndrome (AWS) have prompted the exploration of baclofen's potential role in treating AWS. While the data on baclofen's efficacy in treating AWS are mixed, the safety profile is consistently supported [6]. Literature, mainly consisting of case reports and series, indicates that baclofen doses up to 275 mg daily have been used safely. However, there is limited safety data regarding high-dose baclofen use in alcohol-dependent patients, with significant adverse events reported, including overdose and seizures [9].

Baclofen works by activating GABAB receptors, which can inhibit surrounding dopamine neurons. This mechanism reduces alcohol-stimulated dopamine release, decreasing the positive reinforcement associated with alcohol consumption and supporting abstinence. In addition, evidence suggests that baclofen is a safe maintenance treatment for alcohol dependence, even in cases where patients continue or resume alcohol consumption. Mesolimbic dopamine neurons, located

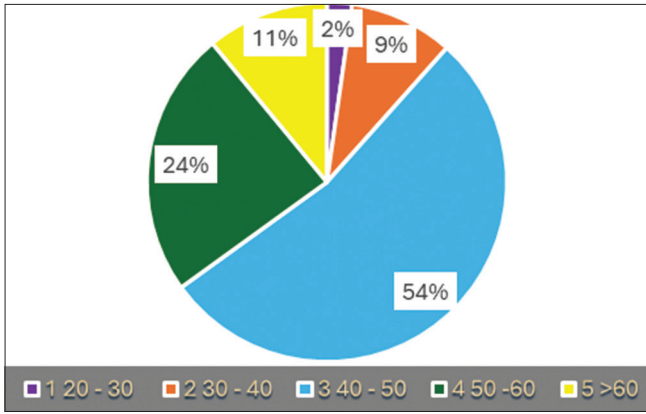


Fig. 1: Subjects distribution based on age

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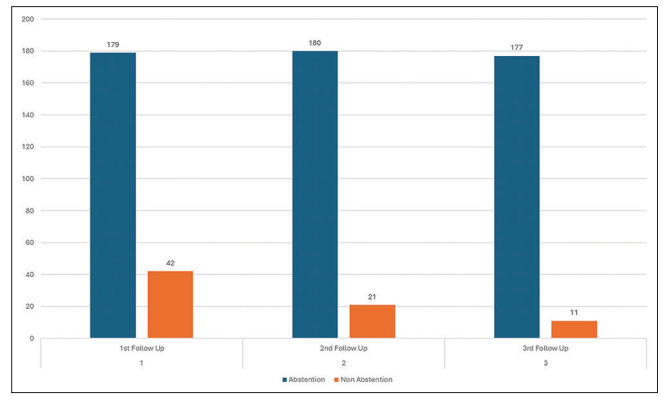


Fig. 5: Subjects categorization based on alcohol abstinence (baclofen)

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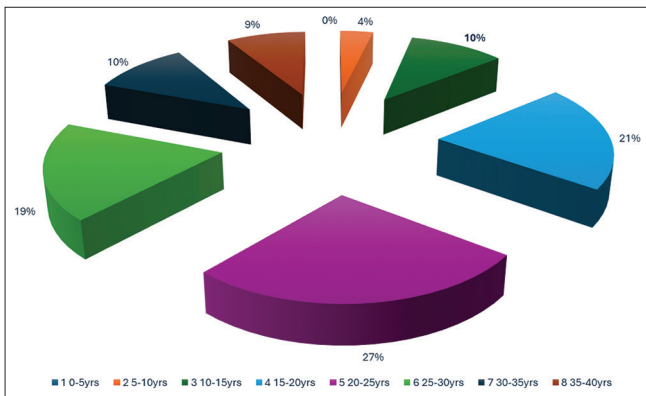


Fig. 2: Subjects distribution based on alcohol intake

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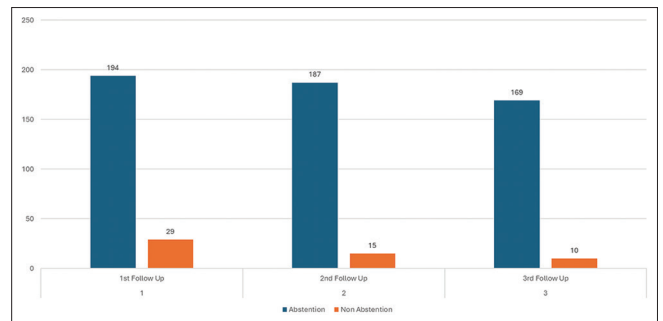


Fig. 6: Subjects categorization based on alcohol abstinence (Librium)

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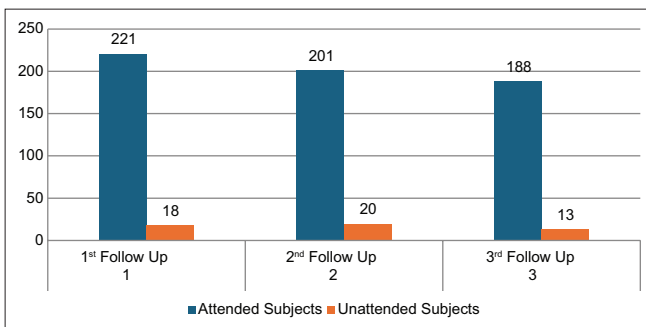


Fig. 3: Subjects categorization based on attendance in three follow-ups (baclofen)

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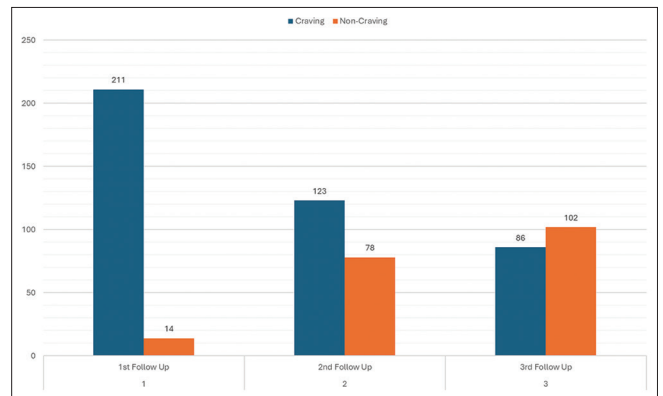


Fig. 7: Craving and non-craving for alcohol in subjects (baclofen)

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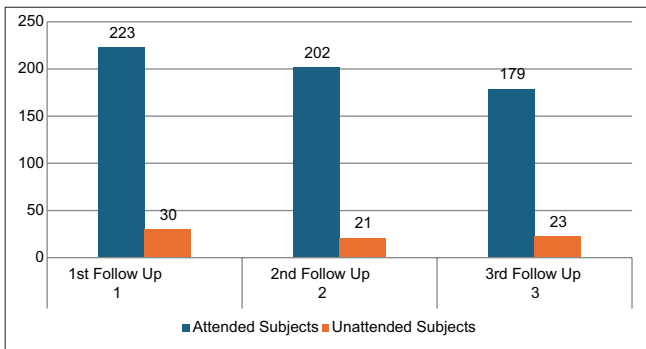


Fig. 4: Subjects categorization based on attendance in three follow-ups (Librium)

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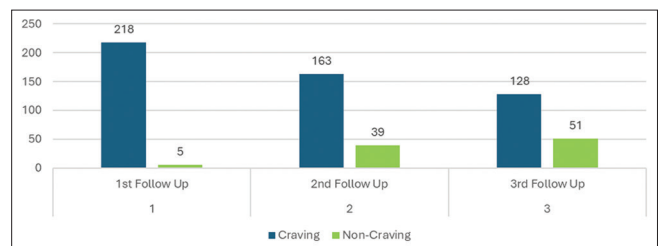


Fig. 8: Craving and non-craving for alcohol in subjects (Librium)

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in areas of the brain where GABAB receptors are found, are thought to play a key role in regulating alcohol intake and reinforcement [10].

Librium (chlordiazepoxide) is a medication commonly used to manage anxiety, alcohol withdrawal symptoms, and muscle spasms. It

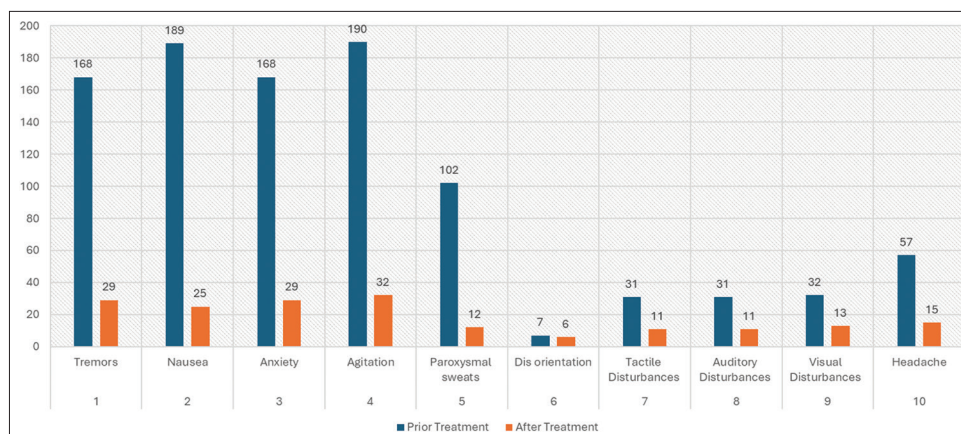


Fig. 9: Subjects distribution before and after treatment (Baclofen)

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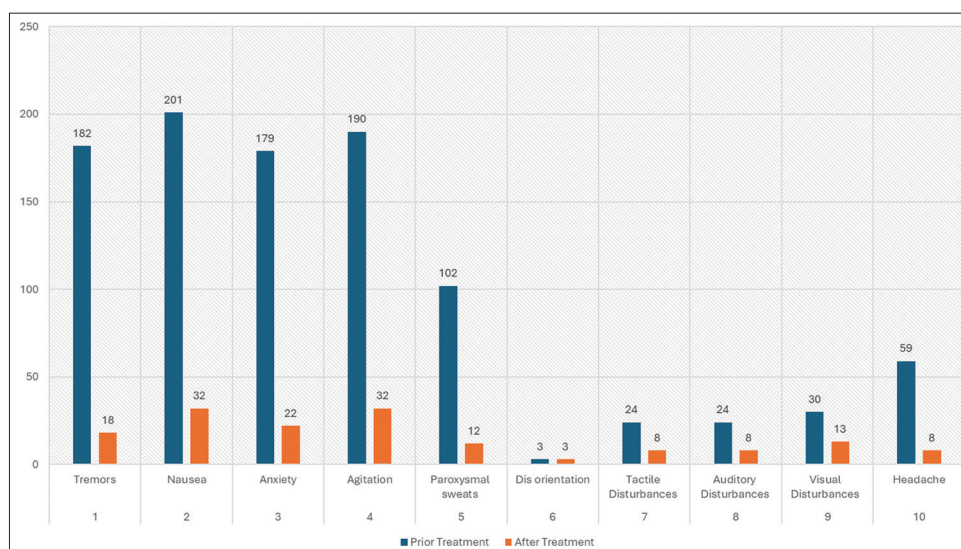


Fig. 10: Subjects distribution before and after treatment (Librium)

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is part of the benzodiazepine class of drugs and works by enhancing the effects of the neurotransmitter GABA, which has a calming effect on the CNS [8].

Librium is frequently used to treat AWS due to its ability to reduce the severity of withdrawal symptoms. Alcohol withdrawal can cause anxiety, agitation, tremors, seizures, and delirium, and benzodiazepines like Librium (chlordiazepoxide) are often prescribed to manage these symptoms. By enhancing GABAergic activity, Librium (chlordiazepoxide) helps to suppress CNS excitability, which is heightened during alcohol withdrawal, reducing the risk of dangerous symptoms such as seizures.

The medication is typically administered in a tapered dose, starting at a higher amount to stabilize the patient, followed by a gradual reduction to avoid withdrawal symptoms from the benzodiazepine itself. Librium (chlordiazepoxide) remains a cornerstone in the management of AWS due to its ability to reduce symptoms and prevent complications. It is essential to use it under medical supervision, as long-term use can lead to dependence and other adverse effects [13].

METHODS

The methodology includes study design, participant selection, sample collection, study procedure, data analysis procedures, and ethical considerations.

Study design

This was a prospective observational comparative study conducted at the Government General Hospital, Nellore, and a tertiary care hospital. The study was approved by the Institutional Review Board (IRB) at Ratnam Institute of Pharmacy with approval number Ratnam/Pharmacy/Res/DPP/IRB/2019-01. This research was designed to evaluate the safety, effectiveness, and anti-craving properties of baclofen and Librium (chlordiazepoxide) in patients with AWS. Patients presenting with symptoms of AWS were assigned either with baclofen (30 mg daily in divided doses) or Librium (50–75 mg daily in divided doses) based on Clinical Institute Withdrawal Assessment (CIWA-Ar) score. Withdrawal symptoms were assessed using the CIWA-Ar scale. All participants provided informed consent before enrollment, and data collection, analysis, and reporting were conducted in accordance with ethical guidelines for research involving human subjects.

Participant selection

The study included subjects who are having symptoms of AWS symptoms. Sample size was determined based on convenience sampling, including all eligible patients during the study period.

Inclusion criteria

- Subjects who agreed to abstain from alcohol for the study duration
- Subjects who agreed to give their consent to the study
- Subjects who were with Alcohol withdrawal symptoms
- Subjects with age of above 18 years.

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Table 1: Subject distribution based on age

S. No.	Age (years)	No. of subjects (%)
1	20-30	11 (2)
2	30-40	46 (9)
3	40-50	263 (54)
4	50-60	118 (24)
5	>60	54 (11)

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Table 2: Subjects distribution based on alcohol intake

S. No.	Alcohol intake in years	Number of subjects
1	0-5 years	2
2	5-10 years	16
3	10-15 years	52
4	15-20 years	102
5	20-25 years	132
6	25-30 years	93
7	30-35 years	52
8	35-40 years	43

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Table 3: Subjects categorization based on attendance in three follow-ups (baclofen)

S. No.	Follow up (baclofen)	Attended subjects (%)	Unattended subjects (%)
1	1 st follow-up	221 (92.4)	18 (7.6)
2	2 nd follow up	201 (90.9)	20 (9.1)
3	3 rd follow up	188 (93.5)	13 (6.5)

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Table 4: Subjects categorization based on attendance in three follow-ups (Librium)

S. No.	Follow-up (Librium)	Attended subjects (%)	Unattended subjects (%)
1	1 st follow-up	223 (88.1)	30 (11.8)
2	2 nd follow-up	202 (90.5)	21 (9.5)
3	3 rd follow up	179 (88.6)	23 (11.4)

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Table 5: Subjects categorization based on alcohol abstinence (baclofen)

S. No.	Follow-up (baclofen)	Abstinence (221) (%)	Non-abstinence (221) (%)
1	1 st follow-up	179 (80.9)	42 (19.1)
2	2 nd follow-up	180 (89.5)	21 (10.5)
3	3 rd follow-up	177 (94.1)	11 (5.9)

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Table 6: Subjects categorization based on alcohol abstinence (Librium)

S. No.	Follow up (Librium)	Abstinence (223) (%)	Non-abstinence (223) (%)
1	1 st follow-up	194 (86.9)	29 (13)
2	2 nd follow-up	187 (83.8)	15 (6.7)
3	3 rd follow-up	169 (75.7)	10 (4.48)

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Table 7: Craving and non-craving for alcohol in subjects (baclofen)

S. No.	Follow up (baclofen)	Craving (%)	Non-craving (%)
1	1 st follow-up (225)	211 (95.4)	10 (4.6)
2	2 nd follow-up (201)	123 (61.2)	78 (38.8)
3	3 rd follow-up (188)	86 (45.75)	102 (54.25)

Table 8: Craving and non-craving for alcohol in subjects (Librium)

S. No.	Follow up (Librium)	Craving (%)	Non-craving (%)
1	1 st follow-up (223)	218 (97.7)	5 (2.2)
2	2 nd follow-up (202)	163 (80.7)	39 (19.3)
3	3 rd follow-up (179)	128 (71.5)	51 (28.5)

Table 9: Subjects distribution before and after treatment (baclofen)

S. No.	Symptoms	Prior treatment	After treatment
1	Tremors	168	29
2	Nausea	189	25
3	Anxiety	168	29
4	Agitation	190	32
5	Paroxysmal sweats	102	12
6	Dis orientation	7	6
7	Tactile disturbances	31	11
8	Auditory disturbances	31	11
9	Visual disturbances	32	13
10	Headache	57	15

Table 10: Subjects distribution before and after treatment (Librium)

S. No.	Symptoms	Prior treatment	After treatment
1	Tremors	182	18
2	Nausea	201	32
3	Anxiety	179	22
4	Agitation	190	32
5	Paroxysmal sweats	102	12
6	Dis orientation	3	3
7	Tactile disturbances	24	8
8	Auditory disturbances	24	8
9	Visual disturbances	30	13
10	Headache	59	8

Exclusion criteria

- Subjects with any drug dependence
- Subjects with multiple comorbidities
- Subjects with psychiatric disorders
- Subjects with neurological disorders
- Subjects who are not willing to abstain from alcohol during the study duration
- Subjects who are not willing to give their consent to the study.

Study procedure

A data collection form and CIWA-Ar scale were used to collect data from patients after obtaining their informed consent. A total of 492 patients were enrolled in the study. For each participant, clinical information, including age, sex, signs and symptoms, history, treatment pattern, and comorbid conditions, was documented.

Data collection

Initially, baseline data were collected from the patients, including demographic details (age, gender), alcohol consumption history (intensity, duration, and type of alcohol), and any existing serious illnesses. Patients were enrolled using the CIWA-Ar scale, which assesses the symptoms of AWS, and their scores were recorded. Three follow-up assessments were conducted, during which the CIWA-Ar scale was re-evaluated, and the scores were recorded at each follow-up.

Data analysis

Continuous variables were analyzed using paired t-tests for within-group comparisons and independent t-tests for between-group comparisons. Categorical variables, including abstinence and craving,

were analyzed using the Chi-square test. Statistical significance was considered at $p < 0.05$.

RESULTS

This is a prospective observational comparative study; we included subjects based on inclusion and exclusion criteria by taking the subjects consent in the study period. We collected data and determined the effectiveness of baclofen and Librium in 492 subjects. Out of 492 subjects, 367 subjects were attended 3 follow-ups and provided information regarding effectiveness of baclofen, Librium and improvement of their quality of life.

Out of 492 subjects, 263 subjects are found between the age from 40 to 50 years, and 118 subjects' age from 50 to 60 years.

Out of 492 subjects, 422 subjects are found to drinking alcohol more than 15 years.

In the total 492 subjects, we have included 239 subjects for baclofen and 253 subjects for Librium. Out of 239 subjects, 221 attended the first follow-up, 201 attended the second follow-up, and 188 attended the third follow-up.

In the total of 492 subjects, we have included 239 subjects for baclofen and 253 subjects for Librium. Out of 253 subjects, 223 attended the first follow-up, 202 attended the second follow-up, and 179 attended the third follow-up.

In the first follow-up, out of 221 subjects, 179 subjects were abstained from alcohol remaining 42 subjects were continued to take alcohol. In the second follow-up, out of 201 subjects, 180 subjects were abstained from alcohol remaining 21 subjects were continued taking alcohol. In the third, follow-up, out of 188 subjects, 177 subjects in abstention with alcohol.

Out of 223 patients, 194 abstained from alcohol during the first follow-up, whereas the remaining 29 continued to use alcohol. In the second follow-up, 187 of the 202 participants stopped drinking, while the remaining 15 continued to do so. Out of the 179 participants in the third follow-up, 169 were abstaining from alcohol.

Chi-square analysis revealed a significant difference in abstention rates between the two groups at the third follow-up ($\chi^2=8.42$, $p=0.004$), indicating that a higher proportion of Baclofen-treated subjects maintained abstinence compared to those treated with Librium.

In the initial follow-up, 211 of the 221 participants had an alcohol appetite, whereas the remaining 10 did not. Out of the 201 participants in the second follow-up, 123 had an alcohol appetite, whereas the remaining 78 did not. Of the 188 participants in the third follow-up, 86 had an alcohol need, while the remaining 102 did not.

In the first follow-up, out of 223 subjects, 218 subjects were craving for alcohol remaining 5 subjects were non-craving for alcohol. In the second follow-up, out of 202 subjects, 163 subjects were craving for alcohol remaining 39 subjects were non-craving for alcohol. In the third follow-up, out of 179 subjects, 128 subjects were craving for alcohol remaining 51 subjects were non-craving for alcohol.

Chi-square testing demonstrated that Baclofen achieved a significantly greater reduction in alcohol craving at the third follow-up compared to Librium ($\chi^2=14.27$, $p < 0.001$), supporting Baclofen's anti-craving properties.

After the treatment, symptoms include nausea, tremors, anxiety, agitation, paroxysmal sweats, and headache, were decreased significantly.

The mean total CIWA-Ar score decreased from 112.8 ± 14.5 at baseline to 48.7 ± 12.3 at the first follow-up, 32.5 ± 10.6 at the second, and 18.9 ± 8.7

at the third follow-up. Paired t-tests confirmed significant within-group reductions at each follow-up compared to baseline ($p < 0.001$).

Symptoms include nausea, tremors, anxiety, agitation, paroxysmal sweats, headache, visual disturbances, tactile disturbances, and auditory disturbances, were decreased significantly.

The mean total CIWA-Ar score decreased from 115.2 ± 15.1 at baseline to 42.3 ± 11.8 at the first follow-up, 28.7 ± 9.9 at the second, and 20.5 ± 8.1 at the third follow-up. These reductions were also statistically significant within-group ($p < 0.001$).

Independent t-tests were performed to compare the mean CIWA-Ar scores between Baclofen and Librium at each follow-up. The results showed no statistically significant difference at the first follow-up ($p=0.12$), second follow-up ($p=0.35$), or third follow-up ($p=0.45$), indicating that both drugs were similarly effective in reducing overall withdrawal severity.

DISCUSSION

Baclofen has primarily been recognized for its muscle relaxant properties. However, the results from our study suggest that baclofen could also be considered an effective treatment for alcohol withdrawal. As a GABA_B receptor agonist, baclofen increases GABA levels, helping to reduce withdrawal symptoms.

Furthermore, baclofen's use extends beyond AWS and shows promising effects in treating alcohol dependence and addiction. It has also been shown to be safe in managing alcohol-related liver disorders, such as cirrhosis. Growing evidence supports baclofen's safety and efficacy as a maintenance treatment for alcohol withdrawal. The studies reviewed indicate that baclofen possesses anti-craving and abstinence-promoting properties for alcohol.

Librium (chlordiazepoxide) is a medication primarily used to treat anxiety, acute alcohol withdrawal symptoms, and as a sedative. It is a benzodiazepine, which works by affecting neurotransmitters in the brain to produce a calming effect. Librium (chlordiazepoxide) is used as part of a detoxification regimen to stabilize patients and reduce the severity of withdrawal symptoms, which may indirectly reduce cravings by preventing the more severe and uncomfortable symptoms associated with AWS.

The results were achieved in this study, which includes both baclofen and Librium (chlordiazepoxide), consistently reduced the total CIWA-Ar scores. However, Librium (chlordiazepoxide) provided quicker and more effective control over anxiety and agitation than Baclofen. Baclofen is having anti-craving (54.25%) property than Librium (28.5%). Baclofen-treated patients demonstrated higher abstinence rates at the third follow-up and a significantly greater reduction in craving compared to Librium ($\chi^2=8.42$, $p=0.004$ and $\chi^2=14.27$, $p < 0.001$, respectively).

A preliminary study conducted by Colombo G and colleagues found that baclofen significantly reduced alcohol consumption, with patients achieving complete abstinence. Among the 20 participants in their study, 14 (70%) were able to maintain abstinence. In contrast, in this study involving 69 patients, 27 (39%) were completely abstinent. The authors also suggested that baclofen may have anti-craving properties, a conclusion that aligns with the anti-craving effect observed in the current study.

An open-label study by Flannery BA and colleagues indicated that baclofen is generally well tolerated by alcohol-dependent patients. In their study of 12 participants, 5 (41%) maintained complete abstinence from alcohol. Similarly, in the present study, 27 (39%) of the 69 subjects achieved complete abstinence.

A randomized, open-label, standard-controlled, parallel-group study by Girish K and colleagues found that both baclofen and

chlordiazepoxide consistently reduced the total CIWA-Ar scores. However, chlordiazepoxide provided quicker and more effective control over anxiety and agitation.

Addolorato and colleagues carried out a preliminary clinical study involving 10 patients with heavy alcohol use. Seven of these patients (70%) were able to maintain abstinence throughout the study. In the current study, 27 (39%) of the 69 patients achieved complete abstinence.

In a comparative study by Addolorato and colleagues, baclofen was found to have similar effects to diazepam in reducing the CIWA-Ar score. They focused on four specific items of the CIWA-Ar assessment – sweating, tremors, anxiety, and agitation – and observed significant reductions after baclofen treatment. In this study, improvements were noted in these same four symptoms: sweating (67%), anxiety (53%), tremors (87%), and agitation (57%).

Limitations

This study provides valuable insights. Here are some limitations which can be addressed in future research. A major limitation of the present study was incomplete follow-up and study was conducted in a single health care facility. Some patients could not be tracked due to missing or incorrect contact information and limited awareness of the importance of follow-up. Despite this, data were successfully collected from the remaining participants, allowing us to assess improvements in withdrawal symptoms and treatment outcomes.

CONCLUSION

Based on Patient Outcomes, Librium (chlordiazepoxide) and baclofen both consistently reduced the overall CIWA-Ar scores. However, compared to Baclofen, Librium (chlordiazepoxide) offered faster and more efficient alleviation from the symptoms of alcohol withdrawal. Baclofen demonstrated superior anti-craving properties and higher abstinence at later follow-ups. AWS was another condition for which Baclofen demonstrated encouraging results. Baclofen may become a new treatment option for AWS, according to the study's findings.

AUTHOR CONTRIBUTIONS

All the authors are involved in the review of literature, collection of data, and preparation of the manuscript, and also they were involved in reviewing and editing of the manuscript.

CONFLICTS OF INTERESTS

There are no conflicts of interest for this research

AUTHOR FUNDING

There is no funding for this project.

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AQ4

AQ4

Author Queries???

AQ1: Kindly provide department

AQ2: Please note some references (7,11,12,14-22) are not cited in text and also duplicate references (4,11; 5,10; 8,15; 9,18) are found (highlighted). Please check and cite all references in chronological order

AQ4: Kindly check edit made

AQ5: Kindly cite figures 1-10 in the text part

AQ6: Kindly cite tables 1-10 in the text part