



COMPARATIVE STUDY OF ABSTINENCE RATES IN ALCOHOL DEPENDENT PATIENTS WHO ARE TREATED WITH DISULFIRAM AND NALTREXONE: A PROSPECTIVE STUDY

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ABSTRACT

Background: Alcohol dependence is a chronic relapsing disorder in which pharmacological treatment can improve outcomes when combined with psychosocial interventions. Disulfiram and naltrexone act through different mechanisms and may differ in their ability to maintain abstinence and prevent relapse.

Aim: To compare abstinence rates in alcohol-dependent patients treated with supervised disulfiram and naltrexone.

Materials and Methods: An open-label, prospective, randomized, comparative study was conducted among 80 male patients with alcohol dependence diagnosed according to ICD-10 criteria. Patients were randomized into two groups of 40 each. The disulfiram group received disulfiram 250 mg/day and the naltrexone group received naltrexone 50 mg/day under supervision. Patients were followed for six months with supportive psychoeducation. Abstinence and days to relapse were assessed, while Alcohol Use Disorders Identification Test (AUDIT) scores and gamma-glutamyl transferase (GGT) levels were measured at baseline and at six months. Chi-square test and Student's t-test were used for analysis.

Results: Abstinence was significantly higher in the disulfiram group than in the naltrexone group (70% vs. 40%; $p=0.007$). Mean days to relapse were higher with disulfiram (103.833 days) than with naltrexone (60.1 days). End-of-study AUDIT scores were 10.83 and 14.6 in the disulfiram and naltrexone groups, respectively ($p=0.028$). GGT levels decreased to 78.85 U/L with disulfiram and 147.075 U/L with naltrexone ($p=0.013$).

Conclusion: Supervised disulfiram was associated with higher abstinence, longer time to relapse, and greater reductions in AUDIT and GGT levels than naltrexone.

KEYWORDS: Alcohol Dependence, Disulfiram, Naltrexone, Abstinence, Relapse, Audit, Gamma-Glutamyl Transferase.

Introduction

Alcohol use disorders (AUD) represent a substantial public health problem worldwide[1]. According to the World

Health Organization (WHO) 2011 report, harmful use of alcohol results in approximately 2.5 million deaths each year, with a net loss of life of 2.25 million[1]. Alcohol abuse is also a leading risk factor for death among males

aged 15–59 years, primarily due to injuries, violence and cardiovascular diseases[2]. Globally, 6.2% of all male deaths and 1.1% of female deaths are attributable to alcohol. The Centers for Disease Control and Prevention (CDC) has reported excessive alcohol consumption as the third leading cause of preventable death in the United States[3].

Alcohol dependence is a common, chronic and relapsing medical disorder. Globally and in the United States, alcohol dependence ranks fifth and third, respectively, among preventable causes of morbidity and mortality[3]. Alcohol dependence has a lifetime prevalence of approximately 12.5%, and heavy alcohol use contributes to several medical conditions including hypertension, diabetes, cardiovascular and digestive diseases, depression and liver disease[4,5]. Without a pharmacological adjunct to psychosocial treatment, clinical outcomes are poor, with up to 70% of patients resuming drinking within one year[6].

Alcohol dependence is therefore an important condition requiring effective pharmacological management. Systematic reviews and meta-analyses have shown that pharmacological agents can improve the effectiveness of psychosocial treatment. Important medications include disulfiram, naltrexone and acamprosate. Disulfiram is an alcohol-deterrent drug that inhibits acetaldehyde dehydrogenase, resulting in accumulation of acetaldehyde and producing an aversive reaction following alcohol consumption. Naltrexone is an opioid antagonist that reduces the rewarding effects of alcohol and thereby decreases alcohol craving and consumption[7].

Several studies have compared disulfiram with naltrexone and other pharmacological treatments for alcohol dependence[8,9]. Supervised administration appears particularly important because treatment adherence is a major determinant of the effectiveness of disulfiram.

Despite the availability of pharmacological treatments, differences in treatment response and abstinence remain clinically important. Indian comparative studies have evaluated disulfiram against naltrexone, acamprosate and topiramate, but further evidence from Indian treatment settings remains relevant[10]. The present study was therefore undertaken to compare abstinence rates among alcohol-dependent patients treated with supervised disulfiram and naltrexone. The aim of the study was to compare abstinence rates in alcohol-dependent patients treated with supervised disulfiram and naltrexone.

Materials and Methods

Study Design and Setting

An open-label, prospective, randomized, comparative study was conducted among patients with alcohol dependence attending the Psychiatry Outpatient Department of Vijayawada Institute of Mental Health and Neurosciences (VIMHANS). The study was conducted over one year, from June 2016 to June 2017.

Study Population and Sample Size

The original study enrolled 80 participants, with 40 participants assigned to each treatment group. For the present study, the sample-size requirement was reassessed using a two-group comparison of proportions rather than a prevalence-based formula. Assuming abstinence rates of 70% in the disulfiram group and 40% in the naltrexone group, based on the observed study proportions, with a two-sided α of 0.05, 80% power, and a 1:1 allocation ratio and an anticipated 10% attrition, the estimated requirement was approximately 42 participants per group. The study included 40 participants per group, and all 80 participants completed the 6-month follow-up.

Inclusion Criteria

Male alcohol-dependent patients aged 25–65 years who fulfilled ICD-10 criteria, consented to participate, had a stable family environment and had a responsible relative to ensure treatment compliance and follow-up were included.

Exclusion Criteria

Patients with other substance use disorders other than nicotine dependence, comorbid psychiatric disorders, medical conditions interfering with treatment compliance or contraindicating the study drugs, and routine liver function tests more than three times the normal value were excluded.

Study Procedure

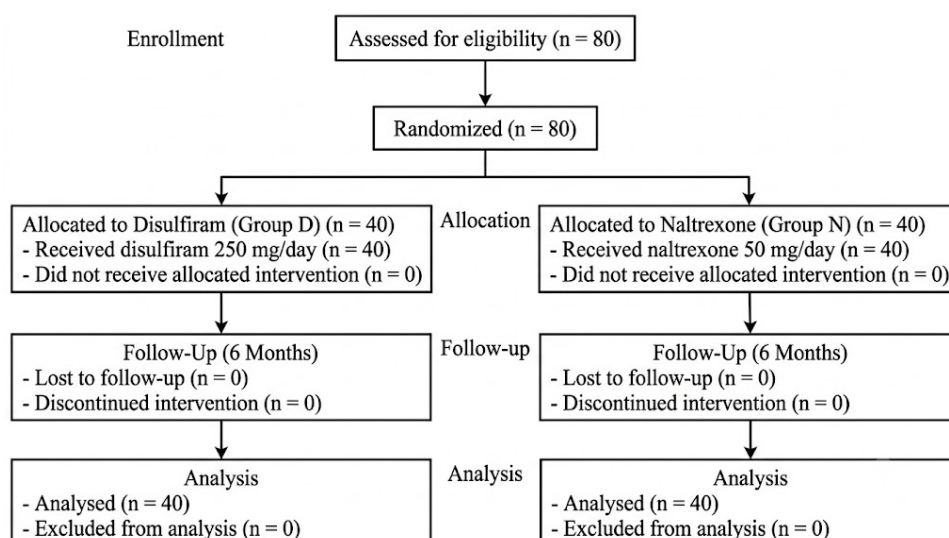
Following outpatient detoxification and treatment of withdrawal symptoms, eligible patients were randomized using computer-generated numbers into two groups. The D group received disulfiram 250 mg/day and the N group received naltrexone 50 mg/day. Patients were informed about the study, treatment duration, medication, mechanism of action and importance of compliance. Medication was supervised in the presence of caregivers, and supportive psychoeducation was provided during follow-up visits.

Assessment and Outcome Measures

The Alcohol Use Disorders Identification Test (AUDIT) was used to assess the alcohol use/risk and alcohol-related problems. Gamma-glutamyl transferase (GGT) levels were measured as a laboratory marker. Abstinence was assessed during follow-up, and relapse was defined as the first alcohol intake after commencement of the study. Abstinence rates and days to relapse were compared between the two groups over a six-month follow-up period. AUDIT scores and GGT levels were assessed at baseline and at the end of the study.

Ethical Considerations

Approval was obtained from the Institutional Ethics Committee before commencement of the study (IEC/16/P/32). Written informed consent was obtained from patients and/or their relatives, confidentiality was maintained, no beneficial treatment was withheld, and no invasive procedure was performed.



Consort Diagram

Statistical Analysis

Data were analyzed using Chi-square test and Student's t-test. Categorical variables including abstinence rates were compared using the Chi-square test, while continuous variables including AUDIT scores and GGT levels were analyzed using Student's t-test. A p value ≤ 0.05 was considered statistically significant.

Results

Table 1, depicts the socio-demographic profile of the two treatment groups. The groups were comparable with respect to age, locality, marital status, religion, education and occupation, with no statistically significant baseline differences. Student's t test was used for the continuous variable (age), while Chi-square test was used for categorical variables.

Table 2, states that the baseline AUDIT scores did not differ significantly between the two groups. At the end of the study, the disulfiram group had a significantly lower mean AUDIT score than the naltrexone group ($p=0.028$). Student's independent-samples t test was used.

Table 3, explains that baseline GGT levels were comparable between the two groups. At the end of the study, GGT levels were significantly lower in the disulfiram group compared with the naltrexone group ($p=0.013$). Student's independent-samples t test was used.

Table 4, depicts that 70% of patients treated with disulfiram remained abstinent compared with 40% of patients treated with naltrexone. The difference in abstinence rates between the two groups was statistically significant ($p=0.007$). Chi-square test, as abstinence was a categorical outcome.

Table 1: Socio-demographic profile of the study participants

Variable	Category	Disulfiram group (n=40)	Naltrexone group (n=40)	p value
Age	Mean age (years)	35.67	37.3	0.22
Gender	Male	40 (100%)	40 (100%)	—
Locality	Urban	26 (65%)	24 (60%)	0.6443
	Rural	14 (35%)	16 (40%)	
Marital status	Married	22 (55%)	23 (57.5%)	0.82
	Unmarried	18 (45%)	17 (42.5%)	
Religion	Hindu	32 (80%)	29 (72.5%)	0.47
	Christian	6 (15%)	10 (25%)	
	Muslim	2 (5%)	1 (2.5%)	
Education	> Matriculate	7 (17.5%)	11 (27.5%)	0.549
	< Matriculate	28 (70%)	24 (60%)	
	Illiterate	5 (12.5%)	5 (12.5%)	
Occupation	Employed	20 (50%)	23 (57.5%)	0.501
	Unemployed	20 (50%)	17 (42.5%)	

Table 2: Comparison of AUDIT scores between the treatment groups

AUDIT score	Disulfiram group Mean	Naltrexone group Mean	p value
At start of study	23.15	21.6	0.15
At end of study	10.83	14.6	0.028*

Table 3: Comparison of GGT levels between the treatment groups

GGT level	Disulfiram group Mean	Naltrexone group Mean	p value
At start of study	377.275	356.75	0.43
At end of study	78.85	147.075	0.013*

Table 4: Comparison of abstinence rates between the treatment groups

Abstinence	Disulfiram group (n=40)	Naltrexone group (n=40)	p value
Yes	28 (70%)	16 (40%)	0.007*
No	12 (30%)	24 (60%)	

Table 5: Comparison of mean days to relapse between the treatment groups

Variable	Disulfiram group	Naltrexone group
Mean days to relapse	103.833 days	60.1 days

Table 5 states that the mean number of days to relapse was higher among patients treated with disulfiram than among those treated with naltrexone. Thus, patients receiving disulfiram remained free from relapse for a longer period during follow-up.

Discussion

The present study demonstrated significantly higher abstinence rates among alcohol-dependent patients treated with supervised disulfiram compared with naltrexone. At six months, 70% of patients in the disulfiram group remained abstinent compared with 40% in the naltrexone group ($p=0.007$). De Sousa et al. (2004) similarly reported that supervised disulfiram was significantly more effective than naltrexone in preventing relapse, with approximately 86% of patients remaining relapse-free with disulfiram compared with 44% with naltrexone. The authors also reported a longer survival time until first relapse with disulfiram[11]. These findings are consistent with the superior abstinence observed with supervised disulfiram in the present study.

Laaksonen et al. (2008)[12] compared disulfiram, naltrexone and acamprostate and found that all three treatments reduced alcohol consumption, while disulfiram was more effective during the continuous medication phase in reducing heavy drinking days and average weekly alcohol consumption and in increasing the time to first drink and number of abstinent days. In the present study, the mean duration to relapse was also longer with disulfiram (103.833 days) than with naltrexone (60.1 days). De Sousa et al[11]. similarly reported a significantly longer time to first alcohol intake with disulfiram than naltrexone. Thus, the present findings support the previously observed advantage of supervised disulfiram in maintaining abstinence and delaying relapse.

The present study also demonstrated a significant reduction

in AUDIT scores with disulfiram compared with naltrexone at the end of follow-up. Baseline scores were comparable between groups, whereas the final mean AUDIT score was 10.83 in the disulfiram group and 14.6 in the naltrexone group ($p=0.028$). Laaksonen et al[12]. reported end-of-treatment AUDIT scores of 27.0 in the disulfiram group and 29.3 in the naltrexone group. Although the absolute values differed between the studies, both findings demonstrate improvement in alcohol-related outcomes following pharmacological treatment, with the present study showing a greater reduction with disulfiram.

The biochemical findings also demonstrated greater improvement with disulfiram. GGT levels were comparable between the groups at baseline but decreased to 78.85 U/L in the disulfiram group compared with 147.075 U/L in the naltrexone group at the end of the study ($p=0.013$). De Sousa et al. (2004)[11] reported reductions in GGT in both treatment groups but did not find a significant difference between disulfiram and naltrexone at the end of treatment. Thus, while both studies demonstrated improvement in GGT, the present study showed a significant between-group difference favouring disulfiram.

The higher abstinence rate and longer time to relapse observed with supervised disulfiram may be related to the treatment's aversive mechanism and the role of supervised medication and family involvement in maintaining compliance. De Sousa et al.[11] reported that disulfiram was particularly effective in alcohol-dependent men with good family support whereas Laaksonen et al.[12] also observed superior performance of supervised disulfiram during continuous medication treatment.

Skinner et al.[13] conducted a meta-analysis of 22 randomized controlled trials evaluating disulfiram for alcohol dependence. Disulfiram showed greater efficacy than controls (Hedges'

$g=0.58$), with superiority particularly evident in open-label studies. It was also more effective than naltrexone ($g=0.77$) and no-disulfiram conditions. The authors concluded that supervised disulfiram is an effective and safe treatment for supporting abstinence in alcohol dependence.

Ray et al.[14] reviewed evidence for behavioral and pharmacological treatments for alcohol use disorder. Naltrexone was identified as the most widely studied pharmacological treatment and demonstrated moderate effect sizes. Cognitive behavioral therapy received the most consistent support among behavioral interventions. The authors emphasized that no single treatment is universally effective and highlighted the importance of individualized treatment approaches.

Overall, the present findings indicate that supervised disulfiram was more effective than naltrexone in maintaining abstinence, delaying relapse and improving AUDIT and GGT measures over six months in this study population.

Conclusion

Supervised disulfiram produced a significantly higher abstinence rate than naltrexone in alcohol-dependent patients. Patients receiving disulfiram had a longer mean duration to relapse than those receiving naltrexone. AUDIT scores showed a significantly greater reduction with disulfiram at the end of six months. GGT levels also showed a significantly greater reduction in the disulfiram group. These findings suggest that supervised disulfiram may be more effective than naltrexone in maintaining abstinence and delaying relapse in this population of male alcohol-dependent patients treated at a single center; given the limitations of the study, these findings should be confirmed by larger, blinded, multicentric trials before wider generalization.

Limitations

This study has certain limitations. The sample size, although close to the calculated requirement, was modest and drawn from a single center, which may limit generalizability; in addition, only male patients were included, so the findings may not extend to women with alcohol dependence. The open-label design could have introduced observer or reporting bias, and the six-month follow-up period was too short to assess long-term outcomes. Abstinence and compliance were assessed mainly through self-report and family report, with GGT as the only biochemical marker. Larger, blinded, multicentric studies with longer follow-up are warranted to confirm these findings.

Declarations

Generative AI was not used in the preparation of the manuscript.

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None

Conflict of Interest

None

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