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Research Article

A COMPARATIVE STUDY OF ALCOHOL CRAVING SCORES BETWEEN PATIENTS RECEIVING NALTREXONE AND ACAMPROSATE FOR ALCOHOL USE DISORDER

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ABSTRACT

Background: Craving drives relapse in alcohol use disorder, but head to head evidence on how naltrexone and acamprosate compare on craving is mixed, and Indian data are scarce.

Methods: A prospective, randomized, open label comparative study was conducted at a rural tertiary care hospital in Telangana from October 2024 to September 2025. It enrolled 120 detoxified adults with alcohol use disorder, 60 per arm, to naltrexone 50 mg or acamprosate 1998 mg daily for 12 weeks. Craving was measured with the Penn Alcohol Craving Scale at baseline, 4, 8 and 12 weeks. Analysis used t tests, chi-square tests and odds ratios with 95% confidence intervals.

Results: Groups were comparable at baseline, with craving scores of 19.2 ± 3.4 and 19.5 ± 3.6. At week 12, naltrexone produced a greater reduction, 13.1 ± 5.0 against 9.4 ± 5.6, mean difference 3.7, 95% CI 1.78 to 5.62, $p<0.05$. Craving response was 75.0% against 51.7%, odds ratio 2.81, 95% CI 1.30 to 6.08. Abstinence was 55.0% against 35.0%, odds ratio 2.27, 95% CI 1.09 to 4.73. Relapse to heavy drinking was 23.3% against 43.3%, odds ratio 0.40, 95% CI 0.18 to 0.87. Nausea was commoner with naltrexone and diarrhoea with acamprosate.

Conclusion: Naltrexone reduced alcohol craving and relapse more than acamprosate over 12 weeks, with an acceptable tolerability profile.

KEYWORDS: Naltrexone, Acamprosate, Alcohol Craving, Alcohol Use Disorder, Penn Alcohol Craving Scale.

Introduction

Alcohol is a leading cause of global ill health. In 2016, alcohol use was the seventh leading risk factor for both deaths and disability adjusted life years, accounting for 2.2% of female and 6.8% of male age standardised deaths, and for 3.8% of female and 12.2% of male deaths at ages 15 to 49 years[1]. In India, the National Mental Health Survey found psychoactive substance use disorders to be the most prevalent group of mental morbidity, at 22.44%, with a treatment gap of 84.5% for overall mental morbidity[2].

Craving is a central driver of relapse, and two drugs are widely used to blunt it after detoxification. Naltrexone is an opioid antagonist, and acamprosate modulates glutamatergic and GABA transmission. A meta-analysis found both reduced return to drinking, but direct comparisons showed no significant difference, with a risk difference of 0.02, 95%

CI −0.03 to 0.08, for any drinking and 0.01, 95% CI −0.05 to 0.06, for heavy drinking[3].

Individual trials disagree. In 157 men followed for a year, 41% on naltrexone and 17% on acamprosate had not relapsed, p=0.0009, and craving was less severe with naltrexone[4]. In 169 patients, an intention to treat analysis found no difference in craving between the drugs[5].

A recent meta-analysis found number needed to treat values of 11 for acamprosate and 18 for naltrexone for any drinking, but only naltrexone reduced heavy drinking, with a value of 11[6]. Indian comparisons are few, and one observational study of 70 patients reported 3 month abstinence of 63.64% with naltrexone against 34.68% with acamprosate, p=0.018[7]. Craving is rarely the primary outcome.

We therefore compared craving scores, response, abstinence and tolerability between naltrexone and acamprosate in patients with alcohol use disorder at a rural tertiary care hospital in Telangana.

Materials and Methods

Study Design

Prospective, randomized, open label, parallel group comparative study, with 1:1 allocation by computer generated random numbers in sealed envelopes.

Study Place and Period

Department of Psychiatry of a rural tertiary care hospital in Telangana, from October 2024 to September 2025. Institutional Ethics Committee approval and written informed consent were obtained.

Sample Size

For comparing two means, the sample size per group was

$$n = 2 \times \sigma^2 \times [\, Z\alpha/2 + Z\beta \,]^2 / d^2$$

where σ is the standard deviation of craving score reduction and d is the minimum clinically important difference. Assuming σ = 5.5, d = 3.0, 95% confidence, Zα/2 = 1.96, and 80% power, Zβ = 0.84, n = 2 × 30.25 × 7.84 / 9 = 52.7, so 53 per group was required. Adding 10% for attrition gave 59, and 60 per group, 120 in total, were enrolled.

Inclusion criteria

- Age 18 to 60 years
- DSM-5 alcohol use disorder, moderate to severe
- Completed alcohol withdrawal management of 7 days
- Baseline Penn Alcohol Craving Scale score of 12 or above
- Written informed consent

Exclusion Criteria

- Opioid use or current opioid medication
- Severe hepatic impairment or renal impairment with creatinine clearance below 30 ml per minute
- Psychosis, bipolar disorder or suicidal risk
- Dependence on other substances except nicotine
- Pregnancy, lactation or hypersensitivity to either drug

Data Assessment Procedure

A structured pro forma recorded age, sex, residence, marital status, duration of drinking and dependence severity by the Severity of Alcohol Dependence Questionnaire. Craving was scored on the Penn Alcohol Craving Scale, five items scored 0 to 6, total 0 to 30, at baseline and at 4, 8 and 12 weeks. Craving response was a reduction of at least 50%. Relapse was five or more standard drinks in a day. Abstinence was no drinking throughout, by self report, collateral informant and breath alcohol at visits. Adverse events were recorded by open questioning and a checklist.

Methodology

Patients received naltrexone 25 mg daily for 3 days then 50 mg daily, or acamprosate 666 mg three times daily, or 333 mg three times daily if under 60 kg. All received thiamine and identical brief psychosocial counselling. Adherence was checked by pill count.

Statistical Analysis

Data were analysed in IBM SPSS Statistics version 26 on an intention to treat basis, with the last observation carried forward. Continuous data are mean ± SD and were compared by the independent t test, with the paired t test for change within groups. Categorical data were compared by the chi-square test, or by Fisher exact test when an expected count was below 5. Odds ratios used the Woolf 95% confidence interval. A two sided p value below 0.05 was considered significant.

Results

All 120 patients were analysed, 60 per arm. Twenty-one discontinued, 7 on naltrexone and 14 on acamprosate.

Table 1, depicts the baseline profile of the two groups. The independent t test was used for continuous variables, the chi-square test for residence and marital status, and the Fisher exact test for sex because only 5 women were enrolled. All p values exceeded 0.05, so the groups were comparable.

Table 2, explains the course of craving, tested at each time point by the independent t test. Scores were similar at baseline but were lower with naltrexone from week 4 onward. The week 12 reduction was 13.1 against 9.4, mean difference 3.7, 95% CI 1.78 to 5.62, Cohen d 0.70. Within groups, the paired t test showed significant falls from baseline to week 12, t = 20.3 for naltrexone and t = 13.0 for acamprosate, both $p<0.05$.

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Table 1: Baseline characteristics

Characteristic	Naltrexone, n=60	Acamprosate, n=60	Test	p value
Age, years, mean ± SD	36.4 ± 8.9	37.8 ± 9.4	t = 0.84	0.40
Male sex, n, %	58, 96.7%	57, 95.0%	Fisher exact	1.00
Rural residence, n, %	41, 68.3%	44, 73.3%	$\chi^2 = 0.36$	0.55
Married, n, %	43, 71.7%	39, 65.0%	$\chi^2 = 0.62$	0.43
Duration of drinking, years, mean ± SD	14.2 ± 6.1	14.9 ± 6.5	t = 0.61	0.54
Dependence severity score, mean ± SD	24.6 ± 6.2	25.1 ± 6.5	t = 0.43	0.67
Baseline craving score, mean ± SD	19.2 ± 3.4	19.5 ± 3.6	t = 0.47	0.64

Table 2: Penn Alcohol Craving Scale scores over time

Time point	Naltrexone, mean ± SD	Acamprosate, mean ± SD	t	p value
Baseline	19.2 ± 3.4	19.5 ± 3.6	0.47	0.64
Week 4	12.1 ± 3.9	14.6 ± 4.2	3.38	<0.05
Week 8	8.2 ± 4.1	11.8 ± 4.5	4.58	<0.05
Week 12	6.1 ± 4.3	10.1 ± 4.9	4.75	<0.05
Reduction at week 12	13.1 ± 5.0	9.4 ± 5.6	3.82	<0.05

Table 3: Treatment outcomes at 12 weeks

Outcome	Naltrexone, n, %	Acamprosate, n, %	Odds ratio, 95% CI	χ^2	p value
Craving response	45, 75.0%	31, 51.7%	2.81, 1.30 to 6.08	7.03	<0.05
Abstinent throughout	33, 55.0%	21, 35.0%	2.27, 1.09 to 4.73	4.85	<0.05
Relapse to heavy drinking	14, 23.3%	26, 43.3%	0.40, 0.18 to 0.87	5.40	<0.05
Completed treatment	53, 88.3%	46, 76.7%	2.30, 0.86 to 6.20	2.83	0.09

Table 4: Craving severity category at week 12

Category	Naltrexone, n, %	Acamprosate, n, %
Low, 0 to 7	38, 63.3%	22, 36.7%
Mild, 8 to 14	18, 30.0%	25, 41.7%
Moderate or severe, 15 or above	4, 6.7%	13, 21.7%

Table 5: Adverse events

Event	Naltrexone, n, %	Acamprosate, n, %	Test	p value
Nausea	15, 25.0%	6, 10.0%	$\chi^2 = 4.68$	<0.05
Dizziness	8, 13.3%	3, 5.0%	$\chi^2 = 2.50$	0.11
Headache	9, 15.0%	7, 11.7%	$\chi^2 = 0.29$	0.59
Diarrhoea	3, 5.0%	14, 23.3%	$\chi^2 = 8.29$	<0.05
Abdominal pain	4, 6.7%	8, 13.3%	$\chi^2 = 1.48$	0.22
Fatigue	7, 11.7%	4, 6.7%	$\chi^2 = 0.90$	0.34
Discontinued for adverse events	3, 5.0%	5, 8.3%	Fisher exact	0.72

Table 3, depicts treatment outcomes compared by the chi-square test. Craving response and abstinence were significantly higher, and relapse significantly lower, with naltrexone. The absolute reduction in relapse, 20.0 percentage points, gives a number needed to treat of 5. Completion did not differ significantly, p=0.09. Of the 7 naltrexone dropouts, 3 were due to adverse events, 3 to loss to follow up and 1 to inefficacy. Of the 14 on acamprosate, 5 were due to adverse events, 5 to loss to follow up and 4 to inefficacy.

Table 4, explains the severity distribution by the chi-square test, $\chi^2 = 10.17$, df 2, $p<0.05$. Low craving was reached by 63.3% on naltrexone against 36.7% on acamprosate, whereas moderate or severe craving persisted in 6.7% against 21.7%.

Table 5, depicts adverse events by the chi-square test,

with Fisher exact test for discontinuation. Nausea was significantly commoner with naltrexone and diarrhoea with acamprosate. Other events and discontinuation for adverse events did not differ, and all events were mild.

Discussion

Naltrexone produced greater craving reduction, response and abstinence, and less relapse, than acamprosate over 12 weeks. We compared our findings with six recent studies and two older trials.

The latest meta-analysis found numbers needed to treat for any drinking of 11, 95% CI 1 to 32, for acamprosate and 18, 95% CI 4 to 32, for naltrexone, and only naltrexone reduced heavy drinking, with a number of 11, 95% CI 5 to 41. It found that four direct comparisons did not consistently favour either drug[6]. Our number needed to treat of 5 for heavy drinking is smaller, probably because of our small, open label sample, but the direction agrees.

A review of 32 trials in 6036 non abstinent patients found no efficacy of naltrexone or acamprosate on total alcohol consumption[8]. Our patients began treatment after detoxification, which may explain the contrast.

An Indian study of 35 patients per arm reported 3 month abstinence of 63.64% with naltrexone against 34.68% with acamprosate, p=0.018, and longer time to first drink and relapse with naltrexone[7]. Our abstinence, 55.0% against 35.0%, matches the acamprosate figure and the direction.

A network meta-analysis found acamprosate reduced return to any drinking against placebo, risk ratio 0.87, 95% CI 0.82 to 0.92, and naltrexone 0.93, 95% CI 0.88 to 0.99, but only naltrexone reduced the secondary outcome, risk ratio 0.87, 95% CI 0.80 to 0.95[9]. This supports naltrexone's edge on heavier drinking.

An All India Institute of Medical Sciences report of 100 men on naltrexone found 72% of retained patients reported significantly less craving, with about a 50% fall in alcohol use [10]. Our craving response on naltrexone, 75.0%, is close. An Indian open label study of 90 men used naltrexone 25 to 50 mg and acamprosate averaging 1021 mg daily, doses like ours, but measured relapse rather than craving[11].

Older trials are mixed. Among 157 men, craving was less severe with naltrexone and 41% against 17% had not relapsed at a year, p=0.0009 [4], in line with ours. Among 169 patients, craving did not differ by intention to treat, with benefit only in low dependence and no depression[5]. A meta-analysis likewise found no difference in direct comparisons, with risk difference 0.02[3]. Our open label design, moderate dependence and short follow up may explain our larger difference.

Naltrexone may blunt alcohol reward and cue driven craving, whereas acamprosate mainly steadies protracted abstinence. The tolerability pattern agrees with the meta-analysis, which reported numbers needed to harm of 9 for nausea with naltrexone and 11 for diarrhoea with acamprosate[3].

Conclusion

Naltrexone reduced alcohol craving, increased abstinence and lowered relapse more than acamprosate in this rural Telangana population, with mild and manageable adverse events. Naltrexone may be preferred as first line anticraving treatment, with acamprosate suited to patients who cannot take it.

Limitations

This was a single centre, open label study with 12 weeks of follow up. Abstinence relied partly on self report, the last observation carried forward method may bias results, and only 5 women were enrolled. Liver function, depression and comorbid drug use were not analysed as modifiers.

Acknowledgements

Nil

Conflict of Interest

Nil

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