Original Article

A randomized comparative trial in the management of Alcohol Dependence: Individualized Homoeopathy versus standard Allopathic Treatment

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Abstract

Objectives: This study was undertaken to compare the effects of IH with standard allopathic (SA) treatment. **Methods:** A randomized controlled, open-label, comparative trial, was conducted, in which alcohol dependents were screened verbally using the CAGE scale. The participants 80 patients fulfilling the inclusion criteria were randomized either IH (n=40) or SA (n=40) and treated cum followed up for 12 months. The primary outcome was more than 50% reduction in the Severity of Alcohol Dependence Questionnaire [SADQ] rating scale at 12th month. Data analysis was done for both intention-to-treat (ITT) and per-protocol (PP) populations. **Results:** ITT analysis reflected 80% (n = 32) of the patients in IH and 37.5% (n = 15) of the patients in the SA responding to CI before 2.4 treatment with absolute difference was 42.5% (42.5 [95% confidence interval [CI]: 23.0, 61.6]) and estimated effect: 6.6 (95% C.I: 2.4, 18.2), P = 0.0002. A significant difference favoring IH was also observed in three out of four domains of WHO QOL-BREF. Statistically significant difference was found in the number of drinking days (median difference: −24.00; CI: −39.0–−8.0; P = 0.001) and number of drinks per drinking day (median difference: −6.3 [95% CI: −11.3–−1.9]; P = 0.004), favoring IH. The results showed a similar trend in PP analysis. Medicines found useful were *Sulphur, Lycopodium clavatum, Arsenicum album, Nux vomica, Phosphorus,* and *Lachesis.* **Conclusion:** The results conclude that IH is not inferior to SA in the management of AD patients. More rigorous studies with large sample size are however desirable.

Key words: Alcohol dependence, Allopathic treatment, Individualized Homoeopathy

Introduction

Alcohol consumption has numerous health and social consequences. It is an important contributor to death and disability. It is estimated to cause about 20–30% of esophageal cancer, liver cancer and cirrhosis of the liver, homicide, epilepsy, and motor vehicle accidents. Worldwide, about 16.0% of the drinkers aged 15 years or older engage in heavy episodic drinking. The prevalence of alcohol use in India is reported to be 21.4%, and it is among the young people with predominantly male gender (4.5%)who are suffering from alcohol dependence (AD). In the country, deaths attributed to alcohol consumption are 62.9% in males.[1]

The standard allopathic (SA) drugs prescribed for AD are *Disulfiram*, *Naltrexone*, *Acamprosate*, and *Baclofen,*[2-4] and SA drugs for alcohol withdrawal are *Diazepam* and *Chlordiazepoxide*.[2] However, long-term use of these drugs leads to side effects, thereby poor compliance to medication, which remain as challenges.[3]

Homoeopathy system of medicine, wherein medicines are prescribed tailored to patient, i.e., individualized to patient (individualized homoeopathy [IH]), has been used in various substance use disorders, such as heroin and alcohol with beneficial effects.[5,6] Homoeopathic treatment has a beneficial role in managing patients with acute alcohol withdrawal symptoms.[7] Observational studies of homoeopathy intervention for AD also direct toward its usefulness in not

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only breaking the cycle of dependence but also in improving alcohol-related sleep disturbances.[8,9]

In a pilot study conducted by Gopinadhan and Balachandran[10] homoeopathic medicine "*Arsenic album*" in alcohol-dependent patients could develop aversion to alcoholic drinks on addition to reduction in the amount and frequency. with this background, this prospective, randomized, controlled, comparative, open-label trial to investigate the effect of IH in managing alcohol-dependent patients compared to SA treatment was undertaken.

Methods

This was a randomized, controlled, comparative, open-label trial of IH and SA treatment in the management of AD, conducted by the Central Council for Research in Homoeopathy at its Central Research Institute, Kottayam, Kerala, India, during October 2012 to October 2014. The study protocol was in accordance with the latest revision of the Helsinki declaration[11] on human experimentation and Good Clinical Practices in India.[12] Although medicines proposed to be used during the study are known homoeopathic pharmacopoeial preparations, yet necessary clearance of the Ethical Committee and Scientific Advisory Committee was obtained before undertaking the study. The study protocol is published[13] and registered with the Clinical Trial Registry of India, registration number CTRI/2011/12/002213.

A random allocation sequence using statistical software had been generated by a statistician independent of the project prior to the commencement of recruitment. Participant allocation to the groups (1:1 ratio) was done immediately after baseline case recording.

Study Population

From the outpatient department of the institute, patients were screened verbally using the Cutting down, Annoyance by criticism, Guilty feeling, and Eye opener scale (CAGE scale)[14] and referred for detailed screening by the research investigator. Patients who met the inclusion/eligibility criteria as per the ICD-10 diagnostic criteria for research of diseases were invited to participate in the trial. Details of eligibility criteria are published elsewhere.[13] All the participants gave their written informed consent before participation into the study and were randomly divided to receive either group of interventions as per the randomization chart.

Intervention

IH treatment was given by a homoeopath. SA treatment was prescribed by the consultant psychiatrist engaged in the trial as per his/her discretion. After enrolment, patients allocated to SA group were treated with *Chlordiazepoxide* along with thiamine for 10–14 days for detoxification. Thereafter, the patients were given medication for AD such as *Baclofen* or *Disulfiram*. The treatment was decided by the consultant. Rescue medication (conventional) in severe withdrawal symptoms such as seizures and delirium tremens, if required, was kept available for prescription by the psychiatrist for patients in both groups. Homoeopathic medicines were procured from Good Manufacturing Practices-certified pharmacy. Supportive assistance in maintaining follow-ups for the study participants was made by a psychiatric social worker (PSW).

Supportive Counseling

Counseling has been given to patients of both the groups by the psychiatrist involved in the study. PSW helped the investigators in motivating patients during treatment and maintaining follow-up through home visits.

Outcome Measures

Primary outcome measure was more than 50% reduction in symptom score in comparison to baseline as per the Severity of Alcohol Dependence Questionnaire (SADQ) at the exit of 1-year treatment period. Apart from baseline, SADQ score was assessed at every 3rd month up to 12 months.

Secondary outcome measures comprise changes in the quality of life (QOL), management of detoxification, and changes in alcohol consumption pattern in terms of quantity and frequency. Two variables were defined retrospectively to answer the secondary outcome parameters for changes in alcohol consumption. Total number of drinking days and number of drinks per drinking day over a 12-month period (the total number of drinks reported during the period divided by the number of days on which consumption of one or more drinks was reported) were calculated. An episode of heavy drinking or relapse was defined as five or more drinks per drinking on a single occasion[15] whereas one standard drink is defined as 30 ml which contains 40% alcohol by volume and 31.2 g/100 ml of absolute alcohol.[16]

The WHO-QOL BREF was also assessed at baseline and at 12 months. The revised Clinical Institute Withdrawal Assessment for Alcohol Scale (CIWA-Ar) was used for the assessment of withdrawal symptoms.

Sample Size

Anticipating the recovery of 90% in SA group and 50% in IH group with noninferiority margin of −10% and to detect this difference with 90% power and one-sided alpha of 2.5%, a total of eighty patients (forty per group) were enrolled.

Statistical Analysis

Statistical analysis was performed in both the per-protocol (PP) and intention-to-treat (ITT) populations using IBM SPSS Statistics version 20. The last observation carried forward method was followed for replacing the missing data. For both ITT and PP groups, comparisons between IH and SA groups were performed at baseline to assess randomization effect using an independent *t*-test for continuous variable and Wilcoxon rank sum test/Chi-square test for ordinal data as applicable. Odds ratio was also calculated to assess the treatment effects. Resulting treatment effects and estimates/size are given together with 95% confidence interval (CI) and corresponding *P* values. In all the analyses, $P < 0.05$ was considered statistically significant.

Results

A total of 109 AD patients were screened. Twenty-nine patients were excluded for not fulfilling the inclusion criteria. Eighty patients were randomized and allocated to either IH group (n = 40) or SA group (n = 40). Eighty patients were analyzed as per the ITT method, and a total of sixty patients (SA = 27 and IH = 33) on regular follow-ups were analyzed PP. Figure 1 shows the flow of the patients in the study.

Both set of patients were comparable at baseline [Table 1]. Mean age of all male patients was 39.9 ± 7.5 and 40.9 ± 9.5 years in IH and SA groups, respectively. Most of the patients were laborers by occupation; 33 (82.5%) in IH and 29 (72.5%) in SA groups. There was no difference in the type of drink consumed between the groups, maximum patients were drinking rum; 14 (17.5%) and 16 (20.0%) in IH and SA groups, respectively. Peer group and work pressure were noticed as the main reasons for drinking alcohol in both the groups. Total SADQ score was 30.1 ± 6.5 and 30.2 ± 7.6 in IH and SA groups, respectively, at baseline ($P > 0.05$).

Efficacy Results: Intention-to-Treat Analysis

AD data for patients who received at least one dose of medication were available for eighty patients (IH: 40; SA: 40). Table 2 shows the results of outcome parameters considered in the study. The primary outcome of treatment response was achieved by 80% (32/40) of the patients allocated to IH and 37.5% (15/40) of the patients in those allocated to SA; the absolute difference in outcome between the treatment groups was 42.5% (95% CI: 23.0–61.6), with $P < 0.0002$ [Table 2]. The proportion of patients who maintained complete abstinence over 12 months' treatment period was achieved by 27.5% (11/40) in IH group and 17.5% (7/40) in SA group. There was no significant difference between relapse and abstinence (95% CI: 8.2–28.2), with $P = 0.28$. A significant difference was found in the total number of drinking days (mean difference −24; 95% CI: −39.0, – 8.0; $P = 0.001$) and total number of drinks per drinking day (mean difference −6.3; 95% CI: −0.4–3.2; 0.004; $P = 0.004$) at 12 months of treatment.

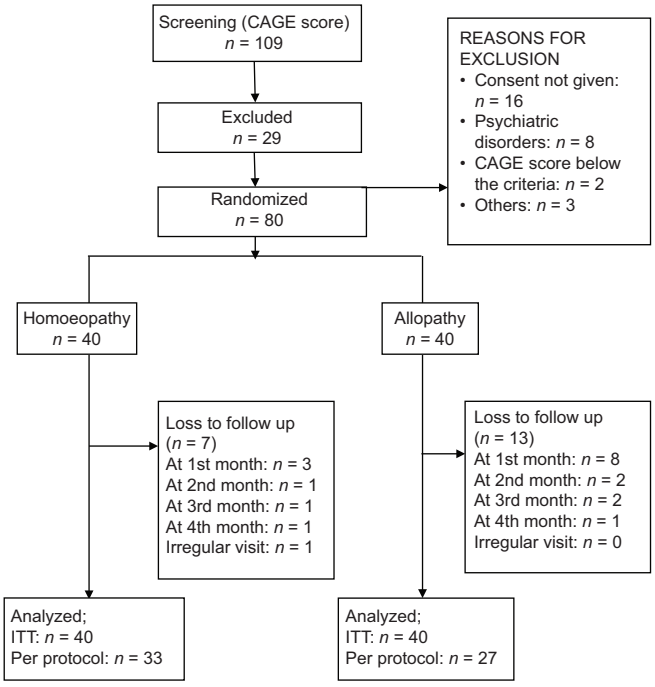

Figure 1: Flow diagram of patients through the trial

The WHO-QOL-BREF score of each patient was calculated at baseline and at 12 months. Statistically significant difference was found in the domains of physical, social, and environment (P = 0.001). No significant difference was obtained in psychological domain ($P > 0.05$) [Table 2]. Trend line showing changes in SADQ score over a period of 12 months is presented [Figure 2] consistently in favor of IH throughout the treatment period of 12 months.

Efficacy Results: Per-protocol Analysis

For protocol-completed and compliant patients, PP analysis was carried out, i.e., IH (n = 33) and SA (n = 27). The primary outcome remained significant: 93.3% (31/33) in IH group and 48.1% (13/27) in SA group; (P = 0.002), similar to ITT analysis. A significant difference was found in the total number of drinking days (mean difference −28; 95% CI: −42.9, – 14; P = 0.0003) and total number of drinks per drinking day (mean difference −7.7; 95% CI: −12.2–−2.9; P = 0.001) at 12 months of treatment.

A significant difference was found in the WHO-QOL BREF domains, i.e environment (P = 0.005), social (P = 0.001), and physical (P = 0.009). There was no significant difference in psychological (P = 0.19) domain [Table 3]. Mean score changes in SADQ score over 12 months showed a positive trend similar to ITT analysis in reduction toward IH as compared to SA from baseline at the exit of treatment period [Figure 3].

Medicines Used and Symptomatic Improvement

The IH medicine was prescribed in either 30 CH or 200 CH potency in a single dose or two doses in the first prescription. Successive prescriptions were either repetition of the same or

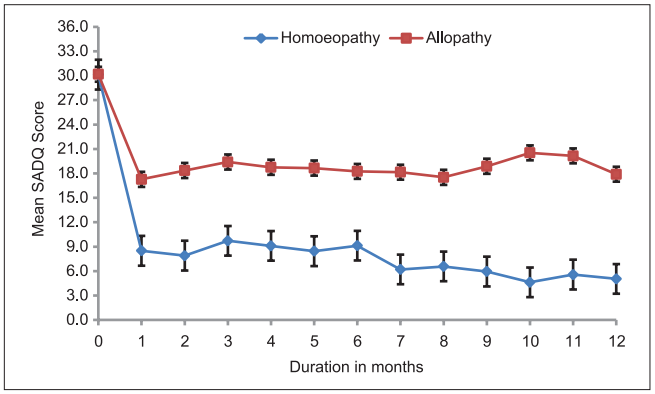

Figure 2: Trend line showing the changes in the mean Severity of Alcohol Dependence Questionnaire score (intention-to-treat)

Table 1: Baseline demographics and clinical characteristics

Variables	All patients (ITT)			Completed and compliant (PP)		
	IH (*n*=40)	SA (*n*=40)	*P*	IH (*n*=33)	SA (*n*=27)	*P*
Age (in years)	39.9±7.5	40.9±9.5	0.60	39.85±7.85	40.93±8.34	0.06*
Marital status						
Married	33 (82.5)	31 (77.5)	-	26 (79.4)	22 (81.5)	-
Single	7 (17.5)	7 (17.5)		7 (20.6)	4 (14.8)	
Divorcee	-	2 (5.0)		-	1 (3.7)	
Occupation						
Laborer	33 (82.5)	29 (72.5)	-	27 (79.4)	19 (70.4)	
Business	4 (10.0)	5 (12.5)		4 (11.8)	4 (14.8)	-
Services	1 (2.5)	4 (10.0)		1 (2.9)	4 (14.8)	
Farmer	2 (5.0)	1 (2.5)		2 (5.9)	-	
Jobless	-	1 (2.5)		-	-	
Age of onset of drinking (in years)	22.9±5.6	22.3±8.2	0.69	22.79±5.7	23.26±7.7	0.78*
Duration of alcohol dependence (in years)	16.9±8.4	18.5±8.9	0.40	17.06±8.8	17.67±7.64	0.77*
Causes of addiction						
Family history	7 (8.8)	5 (6.2)		7 (20.6)	4 (14.8)	
Family conflict	5 (6.2)	3 (3.8)		4 (11.8)	1 (3.7)	
Financial loss	1 (1.2)	2 (2.5)	0.90	1 (2.9)	2 (7.4)	
Peer group pressure	7 (8.8)	11 (13.8)		6 (17.6)	6 (22.2)	
Work pressure	8 (10.0)	7 (8.8)		5 (17.6)	6 (22.2)	0.79#
Reasons not cited	11 (13.8)	11 (13.8)		10 (29.4)	8 (29.6)	
Information not available	1 (1.2)	1 (1.2)		-	-	
Type of drink consumed						
Beer	3 (3.8)	5 (6.3)		3 (8.8)	3 (11.1)	
Brandy	10 (12.5)	11 (13.8)	0.69	8 (23.5)	10 (37.0)	
Rum	14 (17.5)	16 (20.0)		10 (29.4)	10 (37.0)	0.44#
Brandy and rum	4 (5)	2 (2.5)		4 (11.8)	2 (7.4)	
Whisky	1 (3)	2 (2.5)		1 (2.9)	-	
Others	8 (10.0)	4 (5.0)		8 (23.5)	2 (7.4)	
Presenting symptoms						
Abusive	13 (43.3)	17 (56.7)	0.48	10 (7.6)	13 (10.1)	0.76
Craving alcohol	38 (50)	38 (50)	0.69	31 (23.5)	27 (20.9)	0.31
Heaviness of head	9 (100)	-	-	7 (5.3)	0	-
Irritability	21 (44.7)	26 (55.3)	0.25	18 (13.6)	19 (14.7)	0.82
Poor appetite	20 (39.2)	31 (60.8)	0.01	17 (12.9)	23 (17.8)	0.18
Quarrelsome	17 (51.5)	16 (48.5)	0.82	11 (8.3)	11 (8.5)	1.00
Sleeplessness	23 (46.9)	26 (53.1)	0.49	21 (15.9)	18 (14.0)	0.50
Tremors	15 (40.5)	22 (59.2)	0.11	12 (9.1)	13 (10.1)	0.80
Weakness	6 (46.2)	7 (53.8)	0.76	5 (3.9)	5 (3.8)	1.00
Laboratory investigations						
ALT in IU/L				66.6±51.1	60.6±48.3	0.76#
AST in IU/L				70.9±69.6	65.7±45.9	0.81#
AP in IU/L				151.2±69.5	119.2±58.6	0.28#
CIWA-Ar score	4.5±2.2	5.2±3.1	0.24	4.4±1.9	4.4±1.9	0.98*
SADQ score						
Total score	30.13±6.5	30.18±7.6	0.97	30.15±6.8	29.67±7.4	0.79*
Mild (0-16)	0	1 (2.5)		0	1 (3.7)	
Moderate (17-30)	21 (52.5)	23 (57.5)		18 (52.9)	15 (55.5)	
Severe (31 and above)	19 (47.5)	16 (40.0)		16 (47.05)	11 (40.7)	
WHO-QOL BREF						
Physical	44.9±8.5	46.0±11.2	0.62	44.85±8.9	46.07±11.5	0.64*
Psychological	44.8±7.6	45.3±8.4	0.78	44.44±7.7	44.37±7.7	0.97*
Social	50.1±9.7	51.2±10.4	0.62	50.62±9.7	51.52±10.1	0.72*

Contd...

Table 1: Contd...

Variables	All patients (ITT)			Completed and compliant (PP)		
	IH (*n*=40)	SA (*n*=40)	*P*	IH (*n*=33)	SA (*n*=27)	*P*
Environmental	47.1±7.9	45.5±8.6	0.39	47.32±8.0	45.33±9.5	0.38*
Intake of alcohol in pegs per drinking day (1 peg=30 ml)	27.5±10.1	30.0±13.1	0.33	28.23±10.0	16.16±8.3	0.42*

Values are expressed in *n* (%), mean±SD, *Independent *t*-test, #Wilcoxon rank sum test. ITT: Intention-to-treat; PP: Per-protocol; IH: Individualized homoeopathy; SA: Standard allopathic treatment; ALT: Alanine aminotransferase; AST: Aspartate aminotransferase; AP: Alkaline phosphatase; SD: Standard deviation; SADQ: Severity of Alcohol Dependence Questionnaire; WHO-QOL BREF: World Health Organization Quality-of-Life BREF

Table 2: Outcome parameters at 12 months (intention-to-treat)

Variable	IH (*n*=40)	SA (*n*=40)	Mean difference. (95% CI)	*P*	Effect estimate (95% CI)
Primary outcome					
Treatment response (>50% reduction in SADQ score at 12 months)	32 (80)	15 (37.5)	42.5 (23.0-61.6)	0.0002	6.6 (2.4-18.2)
Secondary outcome					
Number of patients abstinent	11 (27.5)	7 (17.5)	10 (8.2-28.2)	0.28	1.7 (0.6-5.2)
Number of patients relapsed	29 (72.5)	33 (82.5)	10 (8.2-28.2)	0.28	0.5 (0.2-1.6)
Total number of drinking days	7 (5–21)	33.0 (12.5-63.5)	−24.0 (−39.0-−8.0)	0.001	
Total number of drinks per drinking day (in pegs)	13.3 (7.7–16.7)	17.6 (12.7-27.9)	−6.3 (−11.3-−1.9)	0.004	
WHO-QOL domains					
Physical	58.8±9.1	52.0±11.5	6.8 (2.2-11.4)	0.005	0.66 (0.20-1.10)
Psychological	55.4±10.3	51.6±9.8	3.8 (−0.7-8.3)	0.08	0.38 (−0.07-0.82)
Social	69.7±13.6	57.9±12.8	11.8 (5.9-17.6)	0.001	0.89 (0.43-1.34)
Environmental	64.2±12.6	54.8±12.0	9.4 (3.9-14.8)	0.001	0.76 (0.30-1.21)
Investigations					
AST	20.5±44.8	26.5±48.8	5.9 (−15.4-27.4)	0.58	-
ALT	22.7±43.3	26.3±71.5	3.6 (−23.3-30.7)	0.78	-
AP	−4.0±37.3	−2.7±81.9	1.3 (27.9-30.6)	0.92	-

Values expressed in *n* (%), mean±SD, median (Q1-Q3). SADQ: Severity of Alcohol Dependence Questionnaire; CI: Confidence interval; ALT: Alanine aminotransferase; AST: Aspartate aminotransferase; AP: Alkaline phosphatase; IH: Individualized homoeopathy; SA: Standard allopathic treatment; SD: Standard deviation

change into higher potency up to 1M. There were six different remedies prescribed, namely, *Sulphur, Lycopodium clavatum, Arsenic album, Nux vomica, Phosphorus,* and *Lachesis* during the patients' treatment period. The most frequently prescribed medicines were *Sulphur*:11 (27.5%) and *Nux vomica*: 10 (25%). Details of prescription and their indications are shown in Table 4a and b.

In the SA group, all the patients (*n* = 40) were given *Chlordiazepoxide* along with thiamine for managing alcohol withdrawal symptoms. During follow-up, 12 patients continued the same medication. Twelve were dropped out within 3 months. Other 16 patients were prescribed as follows: *Baclofen* (*n* = 11), *Disulfiram* (*n* = 3), and *Risperidone* (*n* = 2). *Chlordiazepoxide* along with thiamine was given along with the above medicines as and when required. One patient who was on *Baclofen* was put on disulfiram during the follow-up.

Symptomatic improvement of patients in both groups was analyzed. Apart from improvement in craving for alcohol, other frequently associated symptoms found to be improved are mentioned in Table 5. A significant

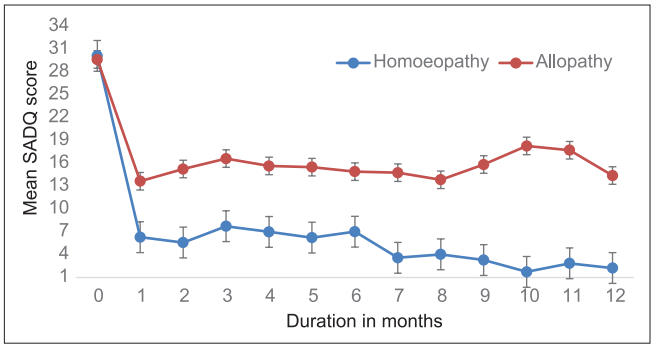

Figure 3: Trend line showing the changes in the mean Severity of Alcohol Dependence Questionnaire score (per-protocol)

difference was found in symptom irritability and craving for alcohol (*P* = 0.001) when compared between IH and SA [Table 5]. There was no reporting of severe withdrawal symptoms, thus none of the patients required rescue conventional medication during the study period in both the groups. CIWA-Ar score was assessed in only two patients who were in SA group and treated with the assigned group medication.

Table 3: Outcome parameters at 12 months (per-protocol)

Variable	IH (*n*=33)	SA (*n*=27)	Mean difference (95% CI)	*P*	Effect estimate/ size (95% CI)
Primary outcome					
Treatment response (>50% reduction in SADQ score at 12 months)	31 (93.3)	13 (48.1)	45.8 (25.2-66.3)	0.0006	16.7 (3.3-84.1)
Secondary outcome					
Number of patients abstinent	10 (43.5)	5 (18.5)	25 (0.04-49.9)	0.29	1.9 (0.5-6.4)
Number of patients relapsed	23 (69.7)	22 (81.5)	11.8 (9.6-33.2)	0.29	0.5 (0.15-1.7)
Total number of drinking days	8 (4-22)	42.5 (22-67.5)	−28.0 (−42.9-−14.0)	0.0003	0.5
Total number of drinks per drinking (in pegs)	13.3 (6.7 to 16.7)	18.6 (15.2 to 28.4)	−7.7 (−12.2-−2.9)	0.001	−0.2
WHO-QOL domains					
Physical	61.2±7.2	55.0±10.5	6.1 (1.57-10.70)	0.009	0.7 (0.2-1.2)
Psychological	56.9±10.5	53.6±9.3	3.3 (−1.76-8.39)	0.19	0.3 (0.2-0.8)
Social	73.7±9.6	61.5±12.1	12.2 (6.41-17.89)	0.001	1.1 (0.6-1.6)
Environmental	76.4±10.4	59.1±11.7	8.33 (2.68-13.98)	0.005	1.5 (0.9-2.1)
Investigations					
AST	30.3±51.4	27.4±51.4	2.8 (−23.8-29.5)	0.83	-
ALT	33.5±72.4	32±48.6	1.5 (−31.0-34.2)	0.92	-
AP	3.2±79.8	−5.7±44.4	8.9 (−23.8-41.7)	0.60	-

Values are expressed in *n* (%), mean±SD; Statistical analysis ¥ODDS ratio, proportion test; *Wilcoxon rank sum test; #Independent *t*-test. CI: Confidence interval; ALT: Alanine aminotransferase; AST: Aspartate aminotransferase; AP: Alkaline phosphatase; IH: Individualized homoeopathy; SA: Standard allopathic treatment; SD: Standard deviation; WHO-QOL BREF: World Health Organization Quality-of-Life BREF

Table 4a: Medicine prescribed in the study

Medicine used	Number of cases	Potency used		
		30 CH	200 CH	1 M
Sulphur	11 (27.5)	1	10	2
Lycopodium clavatum	8 (20)	4	4	1
Arsenic album	6 (15)	4	2	-
Nux vomica	10 (25)	10	0	1
Phosphorus	2 (5)	2	0	-
Lachesis	3 (7.5)	3	0	-

Values are expressed in *n* (%)

Discussion

In this comparative study, IH is noninferior to SA treatment in managing AD. To the best of our knowledge, this is the first and only randomized control trial comparing SA treatment with IH in AD. The primary outcome of treatment response was achieved by 80% of the patients allocated to IH and 37.5% of the patients in SA group. A significant reduction in the number of drinks and drinking days was observed favoring IH compared to SA. Previous studies in homoeopathy are mostly on the management of alcohol withdrawal, but comprehensive management of AD inclusive of alcohol withdrawal was not considered in any of the earlier studies.[4-9] In this study, patients with alcohol withdrawal symptoms were having mild withdrawal symptoms as per the CIWA-Ar score who did not require IPD admission and treated at OPD as per the group assignment. No patient required rescue conventional medication during the study period.

Psychiatric consultant along with homoeopathic investigator had provided abstinent-oriented, supportive, motivational counseling to patients in both the treated groups. Psychological distress and psychiatric morbidity in the spouses of alcohol-dependent men are high, with marital satisfaction being low. Counseling along with treatment had a positive impact on life of patients as eight couples who were on the verge of divorce because of AD reverted back to normal life. Addressing these issues will be beneficial as spouses are known to play an important role in the treatment of AD.[17] This observation should be taken care of in designing future studies on AD.

A nationwide survey on psychoactive substance use in India has found that around 70% of AD are aged 40 years or less.[18] This finding is in consonance with our study, wherein the patient's mean age was 39.9 years in IH group and 40.9 years in SA group.

In another study of homoeopathy in acute alcohol withdrawal, *Arsenicum album, Lycopodium, Nux vomica, Pulsatilla,* and *Belladonna* were useful in the treatment. The quality of life also improved using homoeopathic medicines.[7] In our study also, similar medicines were prescribed for alcohol dependents. Thus, the above group of medicines is found effective in managing not only acute alcohol withdrawal syndrome but also AD.

The SA treatment was given by the consultant psychiatrist engaged in the study as per his discretion. Dosage and regimen were decided by him. The treatment effect in SA group was 3.5, compared to 6.6[19] in IH group. *Disulfiram* has been prescribed to only few patients in our study due to established difficulties with compliance and toxicity.[20]

Effect sizes can be used to determine the sample size for follow-up studies or examining effects across studies.[21] Future

Table 4b: Indications of homoeopathic medicines prescribed in the study

Name of the medicine	Prescribing indications
Arsenicum album	Mental generals Fear at night due to frightful dreams, of being alone and of death. Suspicious, sadness, quarrelsome, scolding, restlessness, nervousness, and desire in alcoholic drinks Physical generals Craves for spices, pickles, desires for coffee, sweets, meat, warm drinks, and foods. Aversion to sweets which increases appetite. Abuse of salt and profuse perspiration. Frequent, liquid thin stool, hemorrhage from anus, hard stools, weakness, thirst for large quantities of water, and sleeplessness Particulars Burning in stomach<after eating, vomiting<morning, after alcoholic drinks. Eczema in extremities and trembling of extremities
Lachesis	Mental generals Desire for alcohol drinks, ailments from grief, sorrow, and care, disappointed love, abusive, anger, extroverted, aversion to work, destructiveness, sensitive, and irritability Physical generals Desires for sour and acids, scanty perspiration, diminished appetite, sleeplessness Particulars Center of tongue cracked and fissured, sensation of ball rising from stomach to throat, black-colored stool, hard stool, ineffectual urging and straining of stool, burning pain in rectum, nausea, and trembling hands
Lycopodium	Mental generals Suspicious, anger from contradiction, intolerant of contradiction, weakness of memory, reserved, abusive, sadness from mental depression, weeping tendency, dipsomania, introverted, irritability, dreams of animals, frightful dreams, dreams of death, dreams of dead people, sensitive, loathing of life, obstinate, forsaken feeling, carelessness, quarrelsome when intoxicated Physical generals Craves for sweets, hot foods, warm drinks, spicy, cold drinks, desires alcoholic drinks. Profuse perspiration, poor appetite, often thirst for small quantities, sleeplessness after midnight, burning pain during urination, constipation, baldness, flushes of heat Particulars Hemorrhoids, enlarged liver, fatty degeneration of liver, troublesome erections, numbness in fingers, swelling of lower limb
Phosphorus	Mental generals Desires for alcoholic drinks, frightful dreams, irritability, abusive, quarrelsome, sensitive Physical generals Craves for meat, fish, cold food, desires for spices, salty food, increased thirst, diminished appetite, sleeplessness
Sulphur	Mental generals Irritability, anger, violence, anxiety of conscience, delirium tremens, desires for death, hereditary dipsomania, extrovert, industrious, weakness of memory, quarrelsome, suspicious Physical generals Craves for spices, sour acids, desires for sweets, alcoholic drinks; stimulants, aversion to sweets, increased thirst, sleeplessness, dry skin, sensation of heat, weakness, sensation of heat Particulars Perspiration in cervical region, profuse perspiration in face, dysuria, scanty urine, hard stool, psoriasis, headache from alcoholic drinks, numbness of foot, hands, vomiting, teeth carries, trembling of hands, varices in leg
Nux vomica	Mental generals Abusive during drunkenness, sensitive, delirium tremens, destructiveness, ailments from disappointment, tendency to anger, disobedience, tendency to hurry, irritability, weakness of memory, discontented and dissatisfied, quarrelsomeness, violence, sleeplessness in drunkards Physical generals Craves for meat, coffee, spicy, desires for stimulants, alcoholic drinks, aversion to sour, thirstlessness, profuse perspiration Particulars Perspiration in face, scanty stool, ineffectual urging and straining at stool, diarrhea in drunkards, hemorrhoids in drunkards, crampy and griping pain in stomach, sour eructations, heartburn after eating, jerking of muscles, trembling in drunkards

studies can refer the effect size for sample size calculation which again depends on the research question and the experimental design.

The sample size in our study was small; therefore, a pragmatic study with a large sample size with/without counseling to the patients may be kept in future designs which can be designed to assess the effectiveness. From the experience from this study, it is recommended to develop standard treatment protocols for both the groups, and this needs further exploration in future studies.

Table 5: Outcome status of symptoms presented by patients due to Alcohol dependence

Symptoms	IH		SA		*P*
	Improved	Not improved	Improved	Not improved	
Abusive	9 (30.0)	4 (13.3)	9 (30.0)	8 (26.7)	0.36
Craving for alcohol	33 (43.3)	5 (6.6)	17 (22.4)	21 (27.6)	0.001*
Heaviness of head	6 (66.7)	3 (33.3)	0	0	-
Irritability	18 (38.3)	3 (6.4)	12 (25.5)	14 (29.8)	0.005*
Appetite	16 (31.4)	4 (7.8)	17 (33.3)	14 (27.5)	0.66
Quarrelsome	12 (36.4)	5 (15.2)	10 (30.3)	6 (18.2)	0.62
Sleeplessness	19 (38.8)	4 (8.2)	14 (28.6)	12 (24.5)	0.32
Tremors	14 (37.8)	1 (2.7)	17 (45.9)	5 (13.5)	0.19
Weakness	4 (30.8)	2 (15.4)	2 (15.4)	5 (38.5)	0.17

Data expressed as n (%), *AD symptoms are analyzed as per the availability of data from baseline to 12 months. Chi-square test was done. IH: Individualized homoeopathy; SA: Standard allopathic treatment

Conclusion

The results conclude that IH is not inferior to SA in the management of AD patients. More rigorous studies are desired to validate these results. The outcome can also be used for future designing of studies and comparing results.

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Conflicts of Interest

There are no conflicts of interest.

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मद्य–पान निर्भरता के प्रबंधन में एक क्रमरहित तुलनात्मक परीक्षणः व्यक्ति–अनुसार होम्योपैथी की तुलना में मानक एलोपैथिक चिकित्सा

उद्देश्य

यह अध्ययन मद्य–पान निर्भरता के प्रबन्धन में व्यक्ति अनुसार होम्योपैथी (आई एच) के प्रभावों की मानक एलोपैथिक चिकित्सा (एसए) के साथ तुलना करने के लिए किया गया था।

सामग्री और विधि

केंद्रीय अनुसंधान संस्थान (होम्यो.), कोट्टायम, केरल में एक क्रमरहित नियंत्रित, खुला लेबल, तुलनात्मक परीक्षण किया गया जिसमें मौखिक छंटनी के लिये केस स्केल का उपयोग किया गया। छांटे गए मद्य–पान निर्भर व्यक्तियों को दो दलों में क्रमरहित विभाजित किया गया (आईएच (सं=40) एसए (सं=40))। चिकित्सा और अनुवर्ती जांच करने की अवधि 12 माह थी। 12 माह पश्चात् चिकित्सा प्रतिक्रिया का प्राथमिक परिणाम मापदंड था (झ 'मद्य–पान निर्भरता की अधिकता (एसएडीक्यू)' के दर्जा पैमाने में 50 प्रतिशत कमी)। चिकित्सा के आशय (आईटीटी) और प्रति संलिखित आबादी दोनों के लिए आंकडों का विश्लेषण किया गया।

परिणाम

आईटीटी आंकलन में प्रदर्शित हुआ कि आईएच में 80 प्रतिशत (सं=32) और एसए में 37.5: (सं=15) रोगियों ने एसएडीक्यू के अनुसार चिकित्सा के प्रति प्रतिक्रिया दिखाई, पूर्ण अंतर था 42.5 प्रतिशत (42.5(95 प्रतिशत सीआई 23.0, 61.6), अनुमानित प्रभाव 6.6 (95 प्रतिशत 2.4, 18.2), पी = 0.0002। डब्ल्यूएचओक्यूओएल–ब्रेफ में आईएच के पक्ष में चार में से तीन अधिकार क्षेत्रों में उल्लेखनीय अंतर दिखा। पीने के दिनों की संख्या में (औसत अंतर –24,00; सीआई –39.0 से –8.0; पी=0.001) और प्रतिदिन पीने की मात्रा की संख्या में (औसत अंतर –6.3 (95 प्रतिशत सीआई –11.3 से –1.9); पी=0.004, आईएच के पक्ष में सांख्यिकीय रूप से उल्लेखनीय अंतर पाया गया। परिणामों में प्रति संलिखित प्रोटोकॉल में भी समान रुझान देखे गए। सल्फर, लाइकोपोडीयम क्लैवेटम, आर्सेनिकम एल्बम, नक्स वोमिका, फॉस्फोरस और लैकेसिस औषधियाँ उपयोगी पाई गईं।

निष्कर्ष

परिणामों से निष्कर्ष निकलता है कि आईएच मद्य–पान निर्भर रोगियों के प्रबन्धन में आईएच, एसए से निम्न नहीं है। इन परिणामों की पुष्टि के लिए अधिक श्रमी अध्ययन वांछनीय हैं।

Ensayo comparativo aleatorizado en la gestión de la dependencia del alcohol: tratamiento homeopático individualizado frente al tratamiento alopático estándar

RESUMEN

Objetivos: Homeopáticos libros de texto y de forma preliminar la investigación sugieren el papel beneficioso de la homeopatía individualizada (IH) en la gestión de la dependencia del alcohol (AD). Este estudio se ha realizado para comparar los efectos de la HI con los del tratamiento alopático estándar (TAS).

Material y métodos: Un estudio controlado, aleatorizado abierto, ensayo comparativo, se ha realizado, en el que los dependientes del alcohol fueron seleccionados utilizando la forma verbal (escala CAGE). 80 pacientes que cumplían los criterios de inclusión (ICD-10 criterios de diagnóstico para la investigación), fueron aleatorizados en dos grupos [HI (n=40) o AS(n=40)] y y semen tratado realizó un seguimiento de 12 meses. El parámetro primario fue la respuesta al tratamiento (> 50% de reducción en la escala de valoración SADQ (Severity of Alcohol Dependence Questionnaire) a los 12 meses. Los análisis de los datos se efectuaron tanto en la población de intención-de-tratar (IDT) como en la población por protocolo.

Resultados: El análisis de IDT mostró que el 80% (n=32) de los pacientes con HI y el 37,5% (n=15) de los pacientes con el TAS respondió al tratamiento, según la escala SADQ; diferencia absoluta 42,5% [42,5 (IC del 95% 23,0, 61,6)], efecto estimado 6,6 (IC del 95% 2,4, 18,2), p= 0.0002. También se observó una diferencia significativa que favorecía la HI en el cuestionario WHOQOL-Bref de los dominios físico (p=0,005), social (p=0,001) y del entorno (p=0,001). Se observaron diferencias significativas en el número de días de bebida (mediana de la diferencia. -24,00; IC: -39,0 al -8,0; p=0,001) y en el número de bebidas por día de bebida [mediana de la diferencia -6,3 (IC del 95% -11,3 a –1,9); p=0,004] que favoreceieron la HI. Los resultados mostraron una tendencia similar en el análisis por protocolo. Los medicamentos observados como útiles fueron Sulphur, Lycopodium clavatum, Arsenicum album, Nux vomica, Phosphorus y Lachesis.

Conclusiones: Los resultados concluyen que la HI no es inferior al TAS en el control de los pacientes alcohólicos. Estudios más rigurosos con muestra de gran tamaño son sin embargo deseables.