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Managing acute alcohol withdrawal with Homoeopathy: A prospective, observational, multicentre exploratory study

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ABSTRACT

Background: Alcohol dependence is a common social problem which may be associated with other risk factors and co-morbidities. Abrupt cessation of alcohol intake may provoke an acute alcohol withdrawal phase with varying degrees of signs and symptoms. In conventional medical system, specific pharmacological interventions are used for management of Acute Alcohol Withdrawal (AAW). There exists a need to explore safe and holistic treatment of AAW. The present work reports the results of a prospective, observational, exploratory, multicentre trial (2008–2011) to assess the role of Homoeopathy in AAW.

Materials and Methods: Individualised Homoeopathy was given to 112 patients reporting with AAW. The clinical assessment was done for 05 days using Clinical Institute Withdrawal Assessment Scale of Alcohol-Revised (CIWA-Ar). Post-withdrawal phase, quality of life of patients was assessed at end of 01st, 03rd and 06th month using World Health Organisation quality of life (WHOQOL)- BREF.

Results and Analysis: There was a significant decrease in CIWA-Ar mean scores and increase in quality of life score ($P < 0.001$). The most common remedies used were *Arsenicum album, Lycopodium clavatum, Belladonna, Nux vomica* and *Pulsatilla*.

Conclusion: The results of current observational pilot study suggest the promising use of Homoeopathy in the management of acute alcohol withdrawal. Further studies with large sample size and rigorous design are warranted.

Keywords: Acute alcohol withdrawal, Alcohol dependence, CIWA-Ar, Homoeopathy, Observational study

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INTRODUCTION

Alcohol dependence is a common problem of modern society and is associated with other risk factors and co-morbidities. Individuals addicted to alcohol may not abstain/withdraw themselves from drinking due to craving and apprehension of complaints associated with withdrawal, even though when they want to do so. Studies show

that abrupt cessation of prolonged, sustained ethanol intake leads to Acute Alcohol Withdrawal (AAW).[1] About 50% of alcohol-dependent patients develop clinically relevant symptoms of withdrawal.[2] Management includes assessment of the severity of the patient's symptoms and treatment of the withdrawal symptoms with pharmacological and non-pharmacological approaches. The recognition and treatment of withdrawal symptoms represents the first step in the patient's recovery process.[3] However, insight also plays an important role in addiction, de-addiction and relapse, which varies at different stages of alcohol dependency. It is suggested that insight is compromised in drug addicts, due to an underlying neural dysfunction in the brain regions that modulate interception, behavioural monitoring, self-evaluation and habit formation. However, direct empirical evidence for such impairment in drug addiction is scarce.[4]

Symptoms and signs usually appear within 6–24 hours after cessation of drinking.[5,6] These initial symptoms of AAW intensify and then diminish between 24 to 72 hours;[3,7] however, they may also last for few days. AAW may be accompanied with seizures, delirium tremens, hallucinations, mental confusion, disorientation, delirium, anxiety, depression, sleep disturbances, etc., In addition, alterations in physiology, mood and behaviour may persist after acute withdrawal has subsided, motivating relapse to heavy drinking.[8,9]

Several studies in conventional system of medicine have demonstrated efficacy of drugs like Benzodiazepines, Carbamazepine, Valproic acid, Gabapentin, etc., to treat this condition but are reported to have moderate to high side effects[10] such as drowsiness, dizziness, unsteadiness, nausea, vomiting, anxiety.[11] It has been desired to have safe and effective alternatives for the management of AAW.

In Homoeopathy, a few studies have been conducted favouring homoeopathic intervention. Milewska (1993),[12] reported a case series of 30 male patients who were prescribed *Sulphur* 3X and later other homoeopathic medicines. Patients were followed up for varying days/months. The author reported that *Sulphur* was able to shorten the alcohol withdrawal phase. Yogandar Rai,[13] treated 241 drug addicts addicted to narcotics, tranquilizers, alcohol, cannabis and multiple drugs with homoeopathic medicines and reported an improvement rate of 86%. The outcomes were physician reported. Deodhar[14] *et al.,* reported the results of 25 patients of AAW treated with Homoeopathy, in which 56% cases recovered within 48–72 hours, 32% recovered within 24–48 hours and 12% cases recovered within 72 hours of treatment. However, all of these studies had methodological flaws and improvements were physician reported with no use of validated scales, which could observe the changes.

Keeping in view the shortcomings of earlier studies in Homoeopathy, a prospective, observational study was undertaken to assess the role of Homoeopathy in AAW management with validated outcome measures.

OBJECTIVES

- *Primary*: To evaluate the usefulness of individualized homoeopathic medicines in treatment of acute alcohol withdrawal
- *Secondary:* To assess the change in quality of life.

MATERIALS AND METHODS

Design

A prospective, open label, multicentre, observational study was undertaken at two drug de-addiction centres of Society for Promotion of Youth and Masses (SPYM) to see the role of homoeopathic treatment in the management of AAW. Ethical approval was obtained from the institutional ethical committee of Central Council for Research in Homoeopathy (CCRH). Written informed consent was obtained from all patients before enrolling to the study.

Patient and settings

Study population was recruited from patients seeking treatment at two de-addiction In-Patient-Units (IPU) of SPYM (New Delhi and Darjeeling) during 2008–2011. Patients between 15 –50 years of age, both genders; regular alcohol usage for at least 01 month; brought by family members or self-reported; history of 02 failed abstinence attempts and written informed consent were included. Patients on other medication for alcohol withdrawal, chronic systemic illness, pregnancy or lactating phase and migratory population were excluded [Figure 1].

Treatment and follow-up

Patients were enquired, in detail, regarding complaints, past history, family history, etc., on a pre-defined proforma. The selection of specific medicine for each patient was on the basis of higher value on the repertorization[15] of presenting signs and

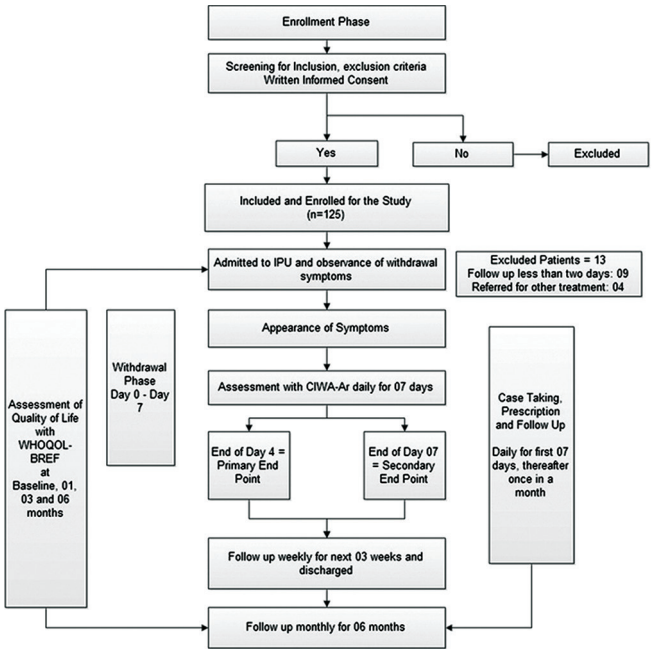

Figure 1: Enrolment and follow up of subjects

symptoms of the patient, further guided by mental/emotional, physical attributes and verification from materia medica. Patients were prescribed 04 pills (globules size 30) of indicated remedy as per the discretion of the treating physician. Patients were seen daily for first 07 days (withdrawal phase), and then at end of 02nd, 03rd and 04th week (observation phase), or at earlier interval, as per need or appearance of new symptoms, if any. During observation phase they were either prescribed non-medicated globules or indicated remedy in infrequent doses. At end of 1st month, patients were either continued at IPU or discharged on request. They were then called for monthly follow up visit for a total of 06 months, and if unable to come, patients were enquired telephonically about their relapse. After 07 days of treatment, patients were motivated for relaxation techniques like meditation, yoga exercise, music, indoor games, etc., for better reinforcement of cognitive abilities, self-confidence, general well-being and social integration.

Outcome measures

The primary outcome measure was total score of Clinical Institute Withdrawal Assessment Scale of Alcohol-Revised (CIWA-Ar),[16] a validated 10-item scale used to monitor the clinical course of alcohol withdrawal symptoms. The CIWA-Ar total score relates to aggregate alcohol withdrawal severity and rater-assessed individual items including evaluation of nausea, tremor, sweating, anxiety, agitation, perceptual disturbances and clouding of sensorium. CIWA-Ar scale has three subcategories according to total score: Mild (<8); Moderate (8–15) and Severe (>15). CIWA-Ar scoring was done daily, at the same time of each day for 05 days. Patients were asked to fill World Health Organisation Quality of Life (WHOQOL)- BREF[17] at baseline, end of 01st, 03rd and 06th month from enrolment.

Statistical methods

The statistical analyses were done with Statistical Package for the Social Sciences (SPSS) version 20. Baseline variables are given using descriptive statistics. Patients who have completed at least two follow ups were considered for the analysis. The missing values were replaced by last assessed value following the Last Observation Carry Forward method. Comparisons of all outcome measures were done using repeated measure analysis of variance (ANOVA). To compare the outcome status of the improvement rate between the follow ups McNemar's test was used. $P < 0.05$ was considered significant.

RESULTS

A total of 125 patients were enrolled, 112 completed the total study duration. Thirteen patients were not included in analysis as 09 patients had follow-up less than two days and 04 patients referred for other treatment within two days of treatment. The data from these patients were not included in the analysis. The baseline characteristics are given in Table 1. Based on CIWA-Ar scores, there were 18 mild patients (16%; score < 8), 54 moderate (48.2%; score 8–15) and 40 severe (35.7%; score >15).

A one-way repeated-measures ANOVA was calculated comparing the CIWA-Ar total scores of patients at five consecutive days, i. e., 0, 1, 2, 3, and 4 and a significant effect was found ($F(4,444) = 487.03$, $P < 0.001$).

The decreasing trend of mean total score CIWA-Ar scale is presented in Figure 2. Similarly, the decreasing trend of mean scores of each sub-domain of CIWA-Ar scale after homoeopathic treatment are presented in Figure 3.

Further, analysis of each subdomain of CIWA-Ar was done using McNemar test, to see the status of patients progressing to improvement/static/worse conditions [Table 2], which showed statistically significant changes ($P = 0.0001$).

The WHOQOL-BREF score of each patient was calculated at baseline, end of 01st, 03rd and 06 months. A one-way repeated-measures ANOVA was calculated

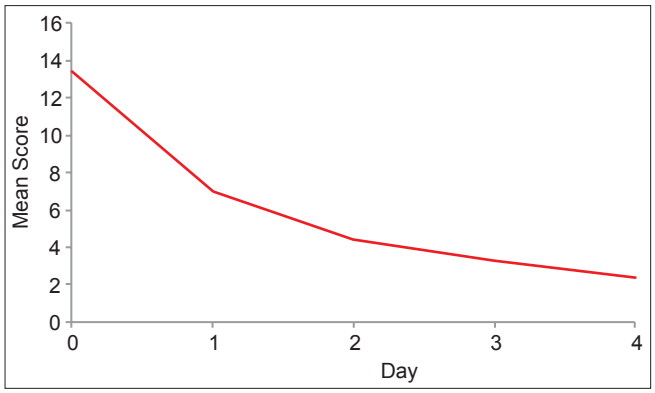

Figure 2: Decrease in mean total score of CIWA-Ar

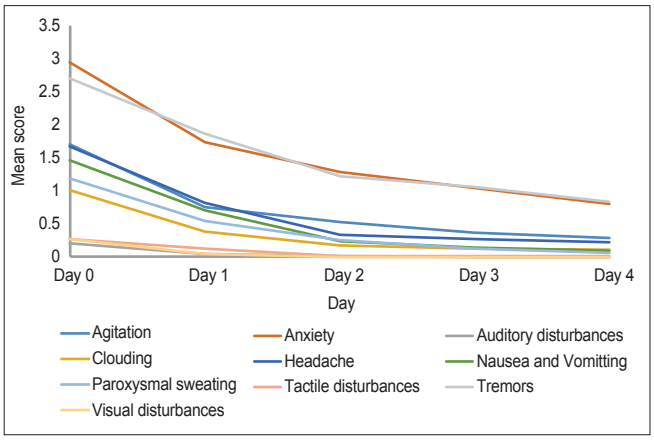

Figure 3: Decreasing trend of each sub-domain of CIWA-Ar after homoeopathic treatment

Table 1: Baseline characteristics (*n*=112)

Variables	*n* (%)	Mean±SD	Median (IQR)
Study centre			
Delhi	64 (57.1)		
Darjeeling	48 (42.9)		
Sex			
Male			
Age group (in years)			
15-18	1 (0.9)	18±0.0	18 (18-18)
19-25	7 (6.3)	23.6±1.3	24 (22-25)
26-35	55 (49.1)	30.1±2.7	30 (28-42)
36-45	40 (35.7)	39.6±2.4	40 (37.8-41.3)
46 and above	9 (8)	48.9±1.5	49 (48-50)
Marital status			
Married	73 (65.2)		
Unmarried	36 (32.1)		
Divorcee	2 (1.8)		
Widow (er)	1 (0.9)		
Alcohol dependence (in years)			
Less than 09	35 (31.2)	6.5+2.1	7 (5-9)
10-19	52 (46.4)	13.6±2.7	13 (11-16)
20-29	20 (17.9)	23.6±3.2	24.5 (22-25.7)
30 and above	2 (1.8)	30+0.0	30 (30-30)
Not specified	3 (2.7)	-	-
Excessive use of alcohol (in years)			
Less than 1	16 (14.3)	0.37+0.23	0.5 (0.1-5.0)
1-10	51 (45.5)	4.01+2.58	4 (2-5)
11-20	5 (4.5)	8.8+1.78	20 (17-20)
More than 20	3 (2.7)	22.6+2.08	22 (21-23)
Not specified	37 (33)	-	-
Age of 1st use of alcohol (in years)			
10-15	28 (25.0)	13.9±1.3	14 (13-15)
15-20	50 (44.6)	17.9±1.5	18 (17-19)
20-25	22 (19.6)	23.1±1.4	23.5 (21.8-24)
25-30	7 (6.3)	28.9±0.9	29 (28-30)
Above 30	5 (4.5)	34.5±3.1	35 (31-36.8)
Quantity of alcohol used in last 30 days (in ml)			
180	10 (8.9)	-	-
360	24 (21.4)		
750	38 (33.9)		
1500	08 (7.1)		
1500	21 (18.8)		
Not specified	11 (9.8)		
Symptoms present			
Agitation	89 (79.5)	1.7±1.3	2 (1.0-3.0)
Anxiety	111 (99.1)	2.9±1.1	3 (2.0-4.0)
Auditory disturbances	21 (18.7)	0.2±0.4	-
Clouding	76 (67.9)	1.0±0.9	1 (0.0-2.0)
Headache	74 (66.1)	1.7±1.5	2 (0.0-3.0)
Nausea and vomiting	64 (57.1)	1.5±1.6	1 (0.0-2.8)
Paroxysmal sweats	68 (60.7)	1.2±1.2	1 (0.0-2)
Tactile disturbances	25 (22.3)	0.3±0.5	-
Tremor	105 (93.7)	2.7±1.3	3 (2-4)
Visual disturbances	20 (17.9)	0.3±0.7	-
Intensity of CIWA-Ar score			
Mild (<8)	18 (16.1)	5.4+1.0	5 (5-6.2)
Moderate (8-15)	55 (49.1)	11.9+2.4	12 (10-14)
Severe (>15)	39 (34.8)	19.2+2.8	19 (16-22)

Values area presented as *n* (%), mean±SD, median (Q1-Q3).
IQR: Interquartile range; SD: Standard deviation; CIWA-Ar: Clinical institute withdrawal assessment scale of alcohol-revised

comparing the WHOQOL-BREF score of patients at four different times: Baseline, month 1, month 3, month 6 and a significant effect was found ($F(3,315) = 137.5$, $P < 0.001$). Further, the subdomains were spider plotted showing the comparative changes at different time point [Figure 4].

Individualized remedies were given on the basis of symptomatic presentation. A common set of remedies has emerged which responded well to AAW, amongst which the most commonly prescribed remedies were *Arsenicum album (n = 38), Lycopodium clavatum (n = 29), Belladonna (n = 14), Nux vomica (n = 13)* and *Pulsatilla (n = 07)*. The suggestive indications of above mentioned remedies are given in Table 3.

About 26 patients (23.2%) went into relapse within 03 months, followed by 16 (14.2%) within 06 months after treatment, but this data was generated out of those patients who opted to entertain the study team during follow-up or telephonically.

DISCUSSION

Alcohol dependence is a major social issue, but since withdrawal symptoms appear only after cessation, the real magnitude of this condition is tip of the iceberg. In the present study homoeopathic intervention was able to manage patients with AAW. The therapy was

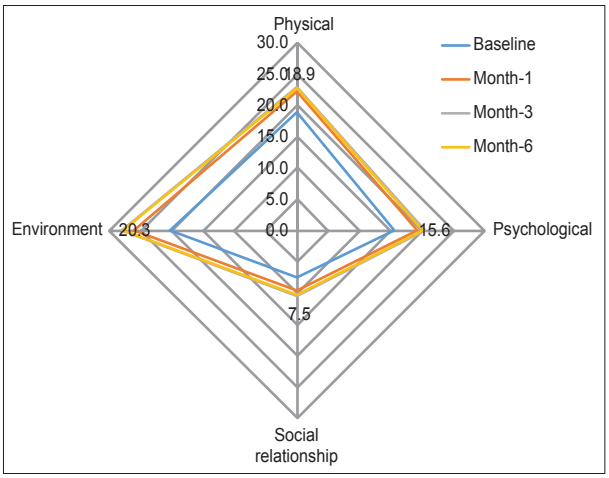

Figure 4: Spider plot of Quality of Life (WHOQOL-BREF)

Table 2: Outcome of patients in subdomains of CIWA-Ar at day4 of treatment, *n*=112

	n (%)			Chi square	*P*
	Improved	Static	Worse		
Agitation	56 (50)	51 (45.5)	05 (0.44)	1.91	0.001
Anxiety	47 (42)	65 (58)	0	1.345	0.001
Auditory disturbances	21 (18.75)	91 (81.25)	0	-	-
Clouding	68 (60.71)	44 (39.28)	0	4.08	0.001
Headache	57 (50.89)	55 (49.1)	0	10.29	0.001
Nausea and vomiting	58 (51.78)	54 (48.21)	0	5.60	-
Paroxysmal sweating	61 (54.46)	51 (45.53)	0	4.83	0.001
Tactile disturbances	24 (21.42)	88 (78.57)	0	3.51	0.001
Tremors	35 (31.25)	77 (68.75)	0	10.97	0.001
Visual disturbances	20 (17.85)	92 (82.14)	-	-	-

Static depicts patients who were either asymptomatic or same as baseline. In McNemar test, only discordant cells are used for data analysis. Accordingly improved and worsened patients have been considered for analysis. For auditory and visual disturbances, all patients improved therefore, McNemar test cannot be applied. Improved: Reduction in score; Static: No change in score; Worse: Increase in score from baseline. CIWA-Ar: Clinical institute withdrawal assessment scale of alcohol-revised

Table 3: Characteristic indications of frequently prescribed medicines

Arsenicum album	Mind: Anxiety about future, health; increased; when alone. Aversion to company, fond of solitude; consolation. Conscientious. Fastidious. Restlessness Physical generals: Burning sensation in general. Weakness of whole body. Perspiration cold; offensive; profuse. Pulse frequent, accelerated, elevated Particulars: Breathlessness. Burning in epigastrium region after eating with nausea; vomiting. Redness of eyes; face. Trembling of hands
Pulsatilla	Mind: Ailments from grief, vexation. Anxiety about his health; conscience of. Attention seeking. Consolation ameliorates. Mildness; timidity; yielding Physical generals: Chilliness in general. Desire tea; open air which ameliorates. Fatty and spicy food aggravates Particulars: Trembling of hands. Bilious vomiting
Belladonna	Mind: Violent anger with fits of rage. Hasty and violent talks. Hyperactivity Physical generals: Coldness in general. Increased thirst. Restlessness Particular: Headache frontal; throbbing. Nausea and vomiting. Redness and congestion of face. Trembling of hands
Lycopodium	Mind: Anticipatory anxiety. Desire to be alone; quite. Dullness and sluggishness of mind. Quarrelsome Physical generals: Appetite decreased. Constipation, unsatisfactory stools. Fat and rich food aggravates. Weakness Particular: Sour eructation. Trembling of hands. Husky voice. Vomiting
Nux vomica	Mind: Anxious and Restlessness. Intolerant to contradiction, gets anger easily. Obstinate, head strong, haughty. Sensitive to mental impressions; slightest noise Physical generals: Appetite decreased. Constipation: Unsatisfactory stools. Sleeplessness Particulars: Heaviness of head. Nausea and vomiting in morning. Tremors of hands. Vertigo

able to annihilate withdrawal symptoms and improve quality of life. In four patients adverse events were noted (seizures, tremors, auditory and visual hallucinations) which are common in patients of AAW. These patients were referred for conventional treatment.

Rai[12] reported remedies like *Avena sativa (Q), Nux vomica (200C), Rhus toxicodendron (10M), Arsenicum album (10M), Bryonia alba (200C), Chamomilla (10M)* to be most useful in drug dependents. Deodhar[14] reported *Zincum metallicum*, *Hyocyamus niger* and *Stramonium* being most commonly used remedies. In our study, most commonly prescribed remedies were *Arsenicum album, Lycopodium clavatum, Belladonna, Nux vomica* and *Pulsatilla*. In earlier works as mentioned, no validated scales/questionnaires were used and the follow-up period varied, whereas the present work quantified the outcome measures with the use of validated scale CIWA-Ar along with a predefined follow-up period.

There were few limitations in our study. Post treatment of acute withdrawal phase, patients were motivated for yoga, exercises, meditation, etc., These factors may have influence on the quality of life outcomes of patients; however, adherence to these advices are not recorded. Inclusion of a control group could have been an additional strength to compare the efficacy of homoeopathic treatment over standard care. Post treatment, the proportion of patients returning for follow-up was not constant, which is a very common issue in Outpatient Department (OPD) settings, therefore, the relapse rate, compliance rate, need for taking of other medicines, post treatment complications, etc., could not be reported fully. The drawbacks may be addressed in future controlled studies.

CONCLUSION

The results of current observational pilot study suggest the promising use of Homoeopathy in the management of acute alcohol withdrawal. Further studies with large sample size and rigorous design are warranted.

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होम्योपैथी के साथ तीक्ष्ण एल्कोहल आहरण का प्रबंधन करना: एक पुरोलक्षी, प्रेक्षणमूलक, बहुकेंद्रीय, समन्वेषी अध्ययन

सार

परिचय: एल्कोहल निर्भरता एक आम सामाजिक समस्या है जो अन्य जोखिम कारकों एवं सह–अस्वस्थताओं से संबद्ध हो सकती है। एल्कोहल के सेवन को अकस्मात् रोक देने से विविध स्तर के संकेतों व लक्षणों के साथ तीक्ष्ण एल्कोहल आहरण प्रावस्था उत्तेजित हो सकती है। पारंपरिक चिकित्सा प्रणाली में, तीक्ष्ण एल्कोहल आहरण (एक्यूट एल्कोहल विदड्रॉअल, एएडब्ल्यू) के प्रबंधन के लिए विशिष्ट भेषजक्रियावैज्ञानिक हस्तक्षेप का उपयोग किया जाता है। एएडब्ल्यू के निरापद एवं समग्रतावादी उपचार का समन्वेष करने की आवश्यकता है। प्रस्तुत कार्य एएडब्ल्यू में होम्योपैथी की भूमिका का आकलन करने के लिए एक समन्वेषी, पुरोलक्षी, खुला नामपत्र, प्रेक्षणमूलक, बहुकेंद्रीय परीक्षण (2008 – 2011) के परिणाम सूचित करता है।

सामग्रियां एवं विधियां: एएडब्ल्यू से पीड़ित स्थिति में आने वाले 112 रोगियों को वैयक्तिकृत होम्योपैथिक चिकित्सा दी गई थी। नैदानिक संस्थान एल्कोहल आहरण आकलन पैमाना – संशोधित (क्लीनिकल इंस्टीट्यूट विदड्रॉअल असेसमेंट स्केल फॉर एल्कोहल – रिवाइज़्ड, सीआईडब्ल्यू–एआर) का उपयोग करते हुए 05 दिनों तक नैदानिक आकलन किया गया था। आहरण चरण पश्चात्, पहले, तीसरे और छठवें माह के अंत पर डब्ल्यूएचओक्यूओएल–बीआरईएफ़ का उपयोग करते हुए रोगियो की जीवन गुणवत्ता का आकलन किया गया।

परिणाम एवं विश्लेषण: सीआईडब्ल्यूए–एआर माध्य समंकों में उल्लेखनीय कमी हुई थी तथा जीवन गुणवत्ता समंकों में वृद्धि हुई थी (चढ0.001)। सर्वाधिक आम रूप से प्रयुक्त औषधियां थीं आरसेनिकम एलबम, लायकोपोडियम क्लावेटम, बेलाडोना, नक्स वोमिका एवं पल्साटिला।

निष्कर्ष: वर्तमान प्रयोगात्मक आरंभिक अध्ययन के परिणाम एएडब्ल्यू के प्रबंधन में होम्योपैथी का आशाजनक उपयोग इंगित करते हैं।

मुख्य शब्द: एल्कोहल निर्भरता, तीक्ष्ण एल्कोहल आहरण, प्रेक्षण मूलक अध्ययन, सीआईडब्ल्यूए–एआर