

A CLINICAL COMPARATIVE STUDY OF THE EFFICACY OF KALYANAKA GHRUTA IN ALCOHOLIC AND NON-ALCOHOLIC ADDICTION W. R. T. PSYCHOLOGICAL SYMPTOMS

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ABSTRACT

Addiction is compulsive need for and use of a habit-forming substance as heroin, nicotine or alcohol. It is categorised as Alcoholic and Non-alcoholic Addiction and those addicts may develop physical and psychological symptoms due to chronic consumption. Research work on this topic regarding the efficacy of various formulations like *Patol- Katurohonyadi kashay*, *Punarnav di Gh ta*, *Kalyanaka Ghruta* etc. have been conducted. This instigated to design a clinical comparative study regarding efficacy of Kalyanaka Ghruta in alcoholic and non-alcoholic addiction with respect to psychological symptoms. The Alcoholic and Non-alcoholic addicts showing psychological symptoms were screened and 20 patients were included in study after obtaining written consent. 10 patients in each group were allotted through randomisation. The *m udu odhan* by *Gandharva- Haritak* was administered at bed time with *ko a jala* for first 7 days in both trial groups. Then the *Kaly aka Gh ta* was given orally in a dose of 20 gm with *ko a jala* at *Ras yana k la* i.e. *pratah k la* and administered nasally as *Nasya* for next 7 weeks. Both groups were weekly observed for 49 days for the psychological symptoms like irritability, insomnia, depression, anxiety which were graded by using W.H.O. guidelines. *Kaly aka Gh ta* showed statistically significant reduction in the psychological symptoms like Depression, Anxiety, Insomnia, Restlessness, Irritability, Delirium and specially the Craving in both groups and equally effective in comparison. It revealed that *Kaly aka Gh ta* is an effective remedy for psychological symptoms due to Alcoholic and Non-alcoholic addiction.

Keywords: *Kaly aka Gh ta*, *Gandharva- Haritak*, *Nasya*.

INTRODUCTION

In today's modern era addictions like alcohol, tobacco chewing, cocaine, smoking, gambling, continuous internet surfing etc. increasing day by day. Generally individuals with poor mental stability and low self control are more prone to addiction. Amongst these along with alcoholic, the incidence of non alcoholic drug addiction e.g. *charas*, *ganja*, opium, antipsychotic tablets etc. is comparatively very

high. Thus alcoholics and non-alcoholics may develop physical and psychological symptoms due to chronic consumption. The psychological symptoms developed are delirium, irritability, insomnia, restlessness, drowsiness, depression, anxiety etc¹.

According to Ayurved, psychological symptoms may be a result of *Dhi-dhruti-smruti bhransh*² causing imbalance

in status of *mann* i.e *karmas* of mind may be altered. Here medicines acting on *manovah strotas* may prove effective in the alleviation of psychological symptoms produced. Vagbhata and Charaka both have stated the usage of *abhyantarprayog* of *Kalyanak ghruta* in *Unmad*³ (insanity), thus empowering *manovaha strotas*. As Psychological symptoms are because of involvement of CNS. Ghruta being a lipid can easily cross the blood brain barrier and acts on CNS; hence *Nasya karma* can prove to be a supportive therapy to its *abhyantarprayog*. In the previous clinical studies, *Kalyanak ghruta* is proven effective in *Unmad*, non-alcohol addictive induced psychological symptoms, chronic alcoholism^{4(a,b,c)}. *Kalyanak Ghruta* is indicated in *Upahat chitta*, *achetasa*, *unmad*, *visha* etc. which may be correlated with the effects of alcohol and non-alcohol additives causing psychological symptoms.

As alcohol and non-alcohol additives are different aetiological factors which produce psychological symptoms. So a comparative study has been designed to know effectiveness of KG against either aetiological factor.

Objectives -

1. To study the efficacy of *Kalyanak Ghruta* in alcoholic and non-alcoholic addiction with respect to psychological symptoms.
2. To compare the efficacy of *Kalyanak Ghruta* in psychological symptoms due to alcoholic and non-alcoholic addiction.
3. To note any other adverse effects observed during the study.

MATERIAL

The trial drug in this study is *Kaly aka Gh ta*. It was purchased from an authorized pharmacy- Vaidyaratnam Pharmacy, Trisur (Kerala). Standardisation

certificate of the formulation has been issued.

METHOD

It is a clinical, randomized, single blind trial study.

The study was conducted at Anandvan De-addiction and Rehabilitation Centre, Chandan Nagar, Pune, following the official permission prior to the conduction of research work.

Inclusion Criteria:-

- 1] Diagnosed patients of alcoholic and non alcoholic addiction showing psychological symptoms.
- 2] Male patients of Age -18 to 45years.

Exclusion Criteria:-

- 1] Patients not willing to give informed consent
- 2] Patients with associated high risk diseases e.g severe jaundice, ascitis, cardiac disorders, liver cirrhosis etc.

Study Design:-

- The Proforma of case paper was designed for screening patients to include in the study.
- Institutional Ethical Committee clearance was obtained prior to commencement of clinical trials.
- Patients of alcoholic and non alcoholic addiction showing psychological symptoms were selected for the study from first week of their IPD admission.
- The selected patients were included in the study after getting written consent.
- These enrolled patients were allotted into two groups through randomization by lottery method.

Group T1 - 10 Patients of alcoholic addiction showing psychological symptoms

Group T2 - 10 Patients of non-alcoholic addiction showing psychological symptoms

- Both groups received same *pathyakar ahar*(diet regimen) and abstinence of alcohol and other addictives as *nidan parivarjana*

Drug Dosage Schedule:-

The Dosage schedule for both the groups was as-

- 1] Pre-medication as a *m du virecana* (mild purgative) - *Gandharav-Haritak* as per *ko tha* at bed-time for the first 7 days.
- 2] *Abhyantar* seven [Oral administration] - *Kalyanaka Ghruta*-20gm in *ras y na k la i.e.pr taha k la* (early morning) with *ko a jala* (luke warm water) for 7 weeks.
- 3] *Nasya* [Nasal administration] - *Kaly aka Gh uta* - 2 *bindu prati*

nas randhra (two drops in each nostril) in *ras yan k la* for 7 weeks.

Follow Up Schedule:-

Follow up of the assessment parameters was taken on the day 7, 14, 21, 28, 35, 42 and 49.

Subjective Parameters as criteria of assessment:-

According to WHO guidelines, the sign-symptoms were graded on the basis of severity. For psychological symptoms like anxiety-depression-delirium, scales of psychology are used like Hamilton's scale for Depression⁵, Anxiety screening quiz⁶ and Delirium Rating scales⁷.

Table No. 1

Sr. No.	Psychological symptoms	Grade1	Grade 2	Grade 3	Grade 4	Grade 5
1.	Craving	Never	Rarely	Sometimes	Usually	Often
2.	Impaired concentration	Never	Rarely	Sometimes	Usually	Often
3.	Disinclination to work	Never	Rarely	Sometimes	Usually	Often
4.	Irritability	Never	Rarely	Sometimes	Usually	Often
5.	Insomnia	Never	Rarely	Sometimes	Usually	Often

6.	Depression	As per Hamilton Depression Rating scale [3]
7.	Delirium	As per Delirium Rating Scale [4]
8.	Anxiety	As per Anxiety Screening Quiz [5]

OBSERVATIONS and RESULTS

Observations were grossly classified into General Observations and Observations of Subjective Parameters.

A] General Observations:

In the both trial groups,

- Maximum patients were of 20-35 years age.
- Approximate 50% patients of the trial groups belonging to the Service category.

- Maximum number of patients from both groups had *v tapradh n- pitta prak ti*.
- Maximum number of patients in non-alcoholic group (T2) showed addiction of *Bhanga-Charas-Ganja*, *Antipsychotic* tablets and *Opioids*.

B] Observations of Subjective Parameters:

The psychological symptoms in alcoholic and non alcoholic addicts were having same gradations on day 0 as like on day 7. As *Gandharva Haritaki* was administered for *mrudu virechana* up to days 7

and thereafter *Kalyanak Ghrita* started, so, effect of *Kalyanak Ghrita* were observed after day 7. Hence observations are mentioned at day 7 and regular follow-up was taken weekly up to day 49.

1] Craving

Alcoholic Group: All 10 patients showed craving of grade 5 at day 7 and start reducing from day 28. On day 49, out of 10 patients-2 patients showed grade 3, 4 patients showed grade 2 and 4 patients showed grade 2 reductions in craving.

Non- alcoholic Group: All 10 patients showed craving of grade 5 at day 7 and start reducing from day 21. At day 49, out of 10 patients- 1 patient showed grade 3, 8 patients showed grade 2 and 1 patient showed grade 1 reduction in craving.

2] Anxiety

Alcoholic Group: All 10 patients were having anxiety of grade 4 at day 7 and start reducing from day 21. At day 49, out of 10 patients- 7 patients showed grade 1, 2 patients showed grade 2 and 1 patient showed grade 0 anxiety.

Non- alcoholic Group: All 10 patients were having anxiety of grade 4 at day 7 and start reducing from day 14. At day 49, out of 10 patients- 2 patients had shown grade 2, 5 patients shown grade 1 and 3 patients shown grade 0 anxiety.

3] Depression

Alcoholic Group: All 10 patients manifested with depression of grade 5 at day 7 and it started to reduce from day 21. At day 49, out of 10 patients, 2 patients showed grade 2, 6 patients showed grade 1 and 2 patients showed grade 0 depression.

Non- alcoholic Group: All 10 patients manifested with depression of grade 5 at day 7 and it started to reduce from day 21. At day 49, out of 10 patients-4 patients showed grade 2 and 6 patients showed depression of grade 1.

4] Irritability

Alcoholic Group: All 10 patients showed irritability of grade 5 at day 7 and it started to reduce from day 21. At day 49, out of 10 patients - 3 patients showed grade 2 and 7 patients showed grade 1 irritability.

Non- alcoholic Group: All 10 patients showed irritability of grade 4 at day 7 and it started to reduce from day 14. At day 49, out of 10 patients - 7 patients showed grade 1 and 3 patients showed grade 0 irritability.

5] Insomnia

Alcoholic Group: All 10 patients were having insomnia of grade 5 at day 7 and start reducing from day 14. At day 49, out of 10 patients - 5 patients showed grade 2, 4 patients showed grade 1 and 1 patient showed grade 0 insomnia.

Non- alcoholic Group: All 10 patients were having insomnia of grade 5 at day 7 and start reducing from day 21. At day 49, out of 10 patients - 7 patients showed grade 2 and 3 patients showed grade 1 insomnia.

6] Restlessness

Alcoholic Group: All 10 patients showed restlessness of grade 5 at day 7 and start reducing from day 14. At day 49, out of 10 patients - 5 patients showed grade 2 and 5 patients showed grade 1 restlessness.

Non- alcoholic Group: All 10 patients showed restlessness of grade 5 at day 7 and start reducing from day 14. At day 49, out of 10 patients - 5 patients showed grade 2 and 5 patients showed grade 1 restlessness.

7] Impaired concentration:-

Alcoholic Group: All 10 patients showed impaired concentration of grade 5 at day 7 and it started to reduce from day 14. At day 49, out of 10 patients - 5 patients showed grade 2 and 5 patients showed grade 1 impaired concentration.

Non- alcoholic Group: All 10 patients showed impaired concentration of grade 5 at day 7 and it started to reduce from day 21. At day 49, out of 10 patients - 7 patients showed grade 2 and 3 patients showed grade 1 impaired concentration.

8] Disinclination to work:

Alcoholic Group: All 10 patients showed disinclination to work of grade 5 at day 7 and start reducing from day 14. At day 49, out of 10 patients - 5 patients showed grade 2 and 5 patients showed grade 1 disinclination to work.

Non- alcoholic Group: All 10 patients showed disinclination to work of grade 5 at day 7 and start reducing from day 14. At day 49, out of 10 patients - 3 patients showed grade 2, 6 patients showed grade 1 and 1 patient showed grade 0 disinclination to work.

STATISTICAL ANALYSIS

The Wilcoxon test was used for intra group i.e. analysis between the groups and Mann Whitney-U test for comparative analysis of improvement between groups.

Table No. 2 1] Craving

Craving	Median		Wilcoxon Signed Rank Statistic 'W'	P-Value	Result
	Before Treatment	After Treatment			
Alcoholic	5	2	-2.84	0.00	Significant
Non-Alcoholic	5	2	-2.97	0.00	Significant

The effect of *Kalyanaka Ghruta* on Craving was significant on alcoholic patients and non-alcoholic patients ($P < 0.05$) at 5%

level of significance. Comparative Analysis of improvement between Groups:

	Median Improvement	Mann-Whitney U statistic	P- Value
Alcoholic	3	41	0.529
Non-Alcoholic	3		

Using Mann-Whitney U-Test, P-Value (> 0.05) It is concluded that, the effect of *Kalyanaka Ghruta* is equal in Alcoholic and Non- Alcoholic Group.

Thus by using Wilcoxon test, the effect of *Kalyanaka Ghruta* on other psychological symptoms like Depression, Anxiety, Insomnia, Restlessness, Irritability, Impaired Concentration and Disinclination to work was also significant on alcoholic and non-alcoholic groups ($P < 0.05$) at 5% level of significance.

It also shows equal significance of KG in alcoholic (T1) & non-alcoholic groups (T2) in these psychological symptoms.

In Previous research work it is found that, effectiveness of *Kalyanaka Ghruta* has been tested by conducting clinical trials in non-alcoholics patients showing psychological symptoms. But alcoholic patients showing psychological symptoms did not conduct so far. The psychological symptoms hamper daily activities and disturb the patient, family members, job place and it becomes a serious, worriful, considerable matter. This realization instigated to design this study.

Some minute issues and difficulties were faced during the study, so would like to discuss firstly, so that it would be helpful in further studies and then probable action of *Kalyanak Ghruta* in alcoholics and non-alcoholics showing psychological

DISCUSSION

symptoms based upon literature review and results.

- Drug standardization: *Kalyanak Ghruta* contains 29 herb ingredients and Cow's ghee. The procurement, authentication and standardization were time taking and a lengthy task. The physicians generally prescribe this medicated *ghruta*. So we purchased *Kalyanak Ghruta* from authentic Pharmacy so that we can test a market standard product.
- Drug Dose: In the classical texts of Ayurved, the dose of medicated ghee is stated as 1 *prastha* i.e. 40 ml. But now a day's patients does not comply to consume 40 ml at a time and may induce *utklesh* (nausea). In many hospitals and clinics, the medicated ghee is administered in the dose of 20 ml for shaman purpose. The alcoholic and non-alcoholic addicts showing psychological symptoms have already *agnimadya* i.e. poor status of *agni*. Taking in consideration all above aspects, the *Kalyanak ghruta* has been administered in the dose of 20 ml.
- Place of study: It was not possible to conduct study at OPD level center, as these alcoholic and non-alcoholic addicts showing psychological symptoms need to be admitted. Very few centers were available fulfilling this requirement. After extensive search Anandvan De-addiction center is availed and has agreed and given permission for the study to be conducted there.
- During Observations: It was not so easy to interact with these patients, as many of them were moody, aggressive, drowsy etc. Thus with the help of attendant, sometimes with available relatives, other co-operative patients ex-

amination, interactions and observations were made.

- Statistical analysis: The results may have been statistically significant in intra group and inter group, if sample size could have been increased.
- **Probable Samprapti bhang (Action of *Kalyanak ghruta*)**
- The KG is indicated in *upahat chetas, achetas, unmad, agnimandya* and *visha vyadhi*. The *ghruta* is of *sheeta, snidha, manda, prasana guna* and the *prabhavishesh is vishghna* and *medhya*.
- The medicine was administered by oral and nasal route.
- According to Ayurved, as nasa is the route of *shirobhaga* i.e. *Mastishka* i.e. Brain. As it is *ghruta kalpana*, the *gamitva* is *buddhi nivasit hrudya* and nasal administration too acts on same *sthana*. Thus may have helped to enhance effects of *Kalyanak ghruta*.
- The collective effect may have acted upon *manovah strotas* clearing *buddhi avaran, moh, and chetasdushti* and thus resulting in *cheto-buddhirshuddhi*. Eventually restoring the psychological symptoms produced.
- In modern toxicology, the long term consumption of Alcohol & Non alcohol additives is stated to be acting upon Hippocampus, Basal ganglia, Nucleus accumbens, Limbic system, Cerebellum etc.

This results in neuro-cognitive deficit, degeneration and super activation of receptors located in those areas, bio-chemical changes altering the functions like behaviour, emotions, cognition, perception, memory etc, resulting into psychological manifestations like craving, impairment in memory and concentration, irritability, anxiety, mood alteration etc.

- The KG, as stated previously seen effective in psychological symptoms produced by long term consumption of alcohol and non- alcoholic addictives like ganja, opium etc.
- The *Kalyanak Ghruta* being lipid base, helps to deliver the drugs into CNS crossing BBB.
- The pharmacological action of ingredients of *Kalyanaka Ghruta* is mainly on CNS, as these are effective as anti-oxidant, rejuvenation, antiacetylcholine and seen effective in CNS depression, hallucinations, stimulation etc.
- So *Kalyanak Ghruta* may have acted by nourishing CNS, correcting the superactivation of receptors and the biochemical changes and thus collectively normalizing the altered functions i.e. psychological symptoms produced.
- The clinical comparative study showed KG equally effective in both groups, may be because of similar effects on psychological symptoms though the aetiological factors were different.

CONCLUSION

The clinical study revealed that, *Kalyanaka ghruta* is **equally effective** in alcoholic and non-alcoholic addiction w. R. T. Psychological symptoms’

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Source of support: Nil

Conflict of interest: None Declared