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Research Article

EFFICACY OF MRUDWEEKADI KASHAYA AND KALYANAKA GHRIT NASYA IN THE TREATMENT OF ALCOHOLIC ADDICTION (MADATYAYA)

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KEYWORDS: Mrudvikadi Kashayam & Kalyanaka Ghrita Nasyam, Madatyaya, Alcohol Withdrawal Syndrome.

ABSTRACT

Madatyaya (Alcohol Withdrawal Syndrome) is a crucial problem in India, many people lose their life due to it. *Madya* (Alcohol) is when taken judiciously act like Nector but when used without restriction act like poison and creates symptoms of *Madatyaya* (Alcohol withdrawal Syndrome). It ruins our social mental and economic status. As a doctor it is our responsibility to help such alcohol addicts by counselling and treating them to recover from this addiction. It was with this intention that the disease *Madatyaya* has been chosen for the study.

A study was conducted to access efficacy of "Mrudvikadi Kashayam & Kalyanaka Ghrita Nasyam". 50 patients of Madatyaya were selected in control group and 50 patients in trial group by random selection method. Control group was not given any medicine: however they were observed for 42 days for all parameters. Trial group patients received medications in the form of Gandharva Haritaki for the first 6 days followed by 'Mrudvikadi Kashayam panartha' in the dose of 80ml with Jala (water) in 2 divided dose, morning and evening after food for the duration of 42 days and Kalayanakaa ghrita Pratimarsha Nasya 6 drops in each nostril from day 7 for 42 days. Gradation scale was used for the purpose of case taking; however at the time of statistical analysis Wileoxan test, Mann-Whitney test, Paired t-test, Unpaired t-test were used. It revealed that 'Mrudvikadi Kashayam & Kalyanaka Ghrita Nasya' is effective in Madatyaya. It significantly reduces the symptoms. Agnimandya, Aruchi, Hrullas, Chardi, Daha, Murcha, Gaurav, Kasa, Tandra, Atisweda, Daurbalya and Nidranasha. Both the groups showed better efficacy in alleviation of symptoms of Pralap, Parshwashoola, Trishna and Shirokampa.

'Mrudvikadi Kashayam' is Balya, Rasayana agni deepana and srotoshodhaka and Pachana, and the utility of Kalyanaka ghrita indicates its action on Manovahastrotas by empowering it. 'Mrudvikadi Kashayam' enhances the nutritional status of such alcoholic patients, also appetite and metabolism is increased due to its Deepan karma, which directly affects the Hb level in patients. As Pippali, Yashtimadhu, possesses Vishghna property, 'Mrudvikadi Kashayam' de-toxified the toxic effects of Madya on Liver thus helpful in lowering LFT values. In Madatyaya due to Madya along with Agni dhushti, Srotodushti is also a pathological change. Hence, to treat that Mrudweekadi Kashaya and Kalyanaka Ghrita was selected.

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INTRODUCTION

Addiction is a habitual Psychological and Physiological dependence on a Substance or Practice beyond one's voluntary control. In today's modern, rapid moving, hectic and stressful lifestyle, the common man has a very short time to be cautious of his mental as well as physical health. In result, they lose control over their mind; depict physical or psychological reliance mainly in the form of Alcohol addiction.

It has been noticed that Alcohol addiction affects all strata of society irrespective of age, sex, occupation, economic status, etc. Predominantly individuals with poor mental stability and low self-discipline are susceptible to addiction.

The American Psychiatric Association practice the term Substance dependence instead of drug addiction, which requires at least three of following symptoms be present for diagnosis. (1)

- 1. Tolerance.
- 2. Withdrawal.
- 3. Persistent desire or unsuccessful attempts to reduce the dose.
- 4. Use in larger amount than intended.

- 5. Reduction in social, occupational or recreational activities because of substance abuse.
- 6. Considerable time spent obtaining the substance.
- 7. Continued use despite health, social or economic problems resulting from substance use.

Excess alcohol intake affects every organ of the body which results not only in physical deterioration, but also tremendous social and economic loss, indirectly affecting his entire family. It may lead to neurological disorders, liver cirrhosis, impaired mental function, skeletal myopathy, cardiomyopathy etc.. Besides this, many other withdrawal symptoms like nausea, vomiting, giddiness etc (2)

The classic text of *Ayurved* quotes a similar Vyadhi, *Madatyaya* with its types, symptoms and treatment. Excessive consumption of *Madya* directly affects '*Hriday*' which is one of the vital organs of the body and it is predominantly associated with the *Rasavaha* and *Manovaha Srotas*. ⁽³⁾

According to *Sharangadhar, Madya* is a *Madakari dravya* that affects the *Buddhi* of a person hence Alcohol addiction may be a result of *Dhrutibhransh* in which a person is unable to control his mind viz. *Niyaman karma* of mind is altered. ⁽⁴⁾

Ayurved has prescribed various medicines in the management of *Madatyaya*. Amongst which *Mrudweekadi kashaya* has been quoted to be an effective *Kalpa* in *Sahasrayogam* under the *Madatyaya* chapter. (5) All the *Dravya* in the formulation are *Madhur rasatmaka*, *Madhura vipaki* and *Sita viryatmaka*.

Alcohol addiction being associated with *Manovaha srotas*, a drug like *Kalyanaka ghrita* with its action on *Manovaha srotas dushti* and whose efficacy has been established in alleviation of the psychological symptoms in addiction can also yield good results. Vagbhatacharya too quotes the utility of *Kalyanaka*

ghrita in Bhutgraha, Unmad, Apasmar, Daivopahatcetasi etc. ⁽⁶⁾

According to Charakacharya, *Shodhan* is important in the management of *Madatyaya* thus an apt choice for premedication, *Gandharva Haritaki* is used as it is *Srotoshodhan* and *Anuloman*.

As a doctor, it is our responsibility to help such alcohol addicts by counseling and treating them to recover from this addiction. It was with this intention that the topic has been chosen for the study, which is an earnest endeavor to stem the physical and psychological ill effects of Alcohol Addiction using Ayurvedic formulations.

AIM AND OBJECTIVES

AIM

To clinically assess the efficacy of *Mrudweekadi Kashaya* and *Kalyanaka Ghrit nasya* in the treatment of Alcoholic addiction (*Madatyaya*).

OBJECTIVES

- 1. Procurement of standardized premedication and trial drugs and their utilization in the clinical study.
- 2. To collect the literature on *Madatyaya* and alcoholism according to Ayurvedic classics and contemporary science.
- 3. To collect literature of *Mrudweekadi Kashaya*, its preparation, dosage, uses etc.
- 4. To collect literature of *Kalyanaka Ghrit*, its preparation, dosage, uses etc.
- 5. To assess the incidence of various types of *Madatyaya*.
- 6. To record other effects, if any, during treatment.

MATERIALS AND METHODS

A) Materials

Table 1: Ingredients of Mrudweekadi Kashaya (7)

| Sr. No. | Ingredient | Ingredient Latin Name | |
|---------|-------------|------------------------|--------|
| 1 | Draksha | Vitis vinifera | 1 part |
| 2 | Yashtimadhu | Glycyrrhiza glabra | 1 part |
| 3 | Madhuka | Maduka longifolia | 1 part |
| 4 | Pippali | Piper longum | 1 part |
| 5 | Kharjura | Phoenix dactylifera | 1 part |
| 6 | Chandana | Santalum album | 1 part |
| 7 | Sariva | Hemidesmus indicus | 1 part |
| 8 | Musta | Cyperus rotundus Linn. | 1 part |
| 9 | Ushira | Vetiveria zizanioides | 1 part |
| 10 | Laja | Oryza sativa | 1 part |

Table 2: Ingredients of Kalyanaka Ghrita (8)

| Sr.No. | Ingredients | Latin Name | Praman |
|--------|-------------|-----------------------|---------|
| 1. | Amalaki | Embelica officinalis | 1 Karsa |
| 2. | Bibhitaka | Terminalia belerica | 1 Karsa |
| 3. | Haritaki | Termnalia chebula | 1 Karsa |
| 4. | Vishala | Citrullus colocynthis | 1 Karsa |
| 5. | Bruhat Ela | Amomum subulatum | 1 Karsa |
| 6. | Devdaru | Cedrus deodara | 1 Karsa |
| 7. | Elvaluk | Cucumis sativus | 1 Karsa |
| 8. | Sariva | Hemidesmus indicus | 1 Karsa |

| 9. | Krushnasariva | Ichnocarpus frutescens | 1 Karsa |
|-----|---------------------|------------------------|-----------|
| 10. | Haridra | Curcuma longa | 1 Karsa |
| 11. | Daruharidra | Berberis aristata | 1 Karsa |
| 12. | Shalparni | Desmodium gangeticum | 1 Karsa |
| 13. | Prusniparni | Uraria picta | 1 Karsa |
| 14. | Priyangu | Callicarpa macrophylla | 1 Karsa |
| 15. | Tagar | Valerina wallichi | 1 Karsa |
| 16. | Bruhati | Solanum indicum | 1 Karsa |
| 17. | Kustha | Sessurea lappa | 1 Karsa |
| 18. | Manjistha | Rubia cardifolia | 1 Karsa |
| 19. | Nagkeshar | Mesua ferra | 1 Karsa |
| 20. | Dadima | Punica grantum | 1 Karsa |
| 21. | Vidanga | Embelia ribes | 1 Karsa |
| 22. | Talispatra | Abies webbiana | 1 Karsa |
| 23. | Suksma Ela | Elletarica cardamomum | 1 Karsa |
| 24. | Malati | Jasminum grandiflorum | 1 Karsa |
| 25. | Kamal | Nelombo nucifera | 1 Karsa |
| 26. | Danti | Baliospermum montanum | 1 Karsa |
| 27. | Padmak | Prunus cerasoides | 1 Karsa |
| 28. | Raktachandan | Pterocarpus santalinus | 1 Karsa |
| 29. | Goghruta (Cow ghee) | | 1 Karsa |
| 30. | Jala (water) | | 4 Prastha |

Table 3: Ingredients of Gandharva Haritaki (9)

| Sr. No. | Ingredients | Latin Name | Praman |
|---------|-------------|--------------------|--------|
| 1 | Eranda | Ricinus communis | 1 part |
| 2 | Haritaki | Terminalia chebula | 1 part |

Ready prepared *Mrudweekadi Kashaya* was purchased from Shankar Pharmacy (G.M.P Certified) Kerala, The NOC and standardization certificate has been collected from the pharmacy.

Ready prepared *Kalyanaka Ghrita* was purchased from Shankar Pharmacy (G.M.P Certified) Kerala, The NOC and standardization certificate has been collected from the pharmacy.

Ready prepared *Gandharava Haritaki* was purchased from Shankar Pharmacy (G.M.P Certified) Kerala, The NOC and standardization certificate has been collected from the pharmacy.

B) Methodology

Type of study

Randomized Clinical Study (RCT)

Place of Study

Anandvan De-Addiction and Rehabilitation Centre, Chandan Nagar, Pune. The official permission for conduction of study has been taken from the centre.

Duration of study

The clinical trials were conducted during the period of June 2015 to September 2016.

Criteria of Inclusion

- a. Patients of Alcoholic Addiction.
- b. Age group 18 years and above
- c. Sex Male only

Exclusion criteria

- a. Patients diagnosed with high-risk diseases, e.g. severe jaundice, ascitis, diabetes etc..
- b. Cardiac disorders like IHD, cardiogenic shock, infective Endocarditis etc.
- c. Severe stage of liver cirrhosis, acute hepatitis, liver abscess etc.

Parameters of Assessment

a) Subjective Parameters

The following symptoms were the parameters of assessment.

Table 4: Physical Symptoms (10)

| Sr. No. | Lakshana | Sr. No. | Lakshana |
|---------|------------|---------|---------------|
| 1 | Agnimandya | 11 | Daurbalya |
| 2 | Aruchi | 12 | Shirokampa |
| 3 | Hrullas | 13 | Nidranasha |
| 4 | Chhardi | 14 | Shwasa |
| 5 | Jwara | 15 | Kasass |
| 6 | Daha | 16 | Pralap |
| 7 | Bhram | 17 | Parshwashoola |
| 8 | Staimitya | 18 | Trishna |
| 9 | Gourav | 19 | Tandra |
| 10 | Hikka | 20 | Sweda |

The above symptoms were appropriately graded.

e.g.-Chardi-

1 = 1 - 2 Vega / day

2 = 3 - 4 Vega / day

3 = 5 - 6 Vega / day

4 = above 6 Vega / day

Table 5: Psychological symptoms

| Sr. no. | Psychological symptoms | |
|---------|------------------------|--|
| 1. | Craving | |
| 2. | Depression | |
| 3. | Irritability | |
| 4. | Insomnia | |
| 5. | Restlessness | |
| 6. | Anxiety | |
| 7. | Impaired concentration | |
| 8. | Disinclination to work | |

Criteria for Assessment

Gradation was done on the basis of severity of the complaints according to WHO guidelines.

For psychological symptoms like anxiety-depression-delirium, scales of psychology are used like Hamilton's scale for Depression, Anxiety screening quiz, and Delirium Rating scales.

Table 6: Psychological Scales

| Sr. No. | Symptoms | 1 | 2 | 3 | 4 | 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. | Drowsiness | Never | Rarely | Sometimes | Usually | Often |
| 5. | Flashback | Never | Rarely | Sometimes | Usually | Often |

Table 7: Psychological Scales 2

| 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] |

b) Objective Parameters

- a. Liver Function Test
- b. Haemogram

Study Design

- 1. Ethical clearance was taken. BVDU/COA/30/2014-15 date 15-03-2013 prior to commencement of the study. (Annexure)
- 2. Pre Ph.D. course work examination was held on 23.06.2013 & 25.06.2013.
- 3. After passing Pre Ph.D. course work examination, permanent registration for Ph D work was given on 30.08.2013
- 4. A Special Proforma of the case paper was designed
- 5. Patients diagnosed with *Madatyaya* were selected on the basis of clinical diagnosis.
- 6. Informed consent was taken prior to the commencement of clinical trials.
- 7. Selected patients were randomly allotted to Trial or Control group.
- 8. Patients of both the groups were subjected to laboratory investigations before and after clinical trials.
- 9. Trial group received pre- medication in the form of *Gandharva Haritaki* for the first 6 days followed by

Mrudweekadi Kashaya panartha and Kalyanaka Ghrita as pratimarsha nasya from day 7.

10. The Control group did not receive any trial drugs. However, they had

received the symptomatic treatment of the centre.

11. As per the prevalence of the alcohol addiction in the area of study, the sample size was stated as 100 from the standard sample size formula.

 $N = Z^2 P(1-P) d^2$

Dosage schedule

A) Premedication

| Kalpa | Gandharva Haritaki |
|------------|---------------------------|
| Matra | As per koshtha parikshana |
| Sevan kala | Nisha kala |
| Anupana | Koshna jala |
| Kalavadhi | 6 days |

B) Panartha

| - | | |
|---------------------------|-----------|---------------------------------|
| Kalpa | | Mrudweekadi Kashayam |
| Matra 80 ml in divided do | | 80 ml in divided dose |
| Sevana Adhobh | | Adhobhakta (after meals) |
| kala | | 40 ml morning and 40 ml evening |
| Anupana Jala | | Jala |
| | Kalavadhi | For 6 weeks (42days) |

C] Nasyartha

| • | |
|------------|----------------------------------|
| Kalpa | Kalyanaka Ghrita |
| Kala | Pratahakala |
| Purvakarma | Sadyasnehan-swedan with Til tail |
| Matra | 6 bindu prati nasarandhra |
| Kalavadhi | 6 weeks (42 days) |

• Follow-ups were taken after every 7 days for 49 days i.e. in accordance with the objective parameters.

OBSERVATIONS AND RESULTS

A. Demographic Observations

Table 8: Age wise distribution of Patients

| Age | Trial Group | Trial Group | | Control Group | |
|-------------|-------------|-------------|-----------|---------------|--|
| | Frequency | Percentage | Frequency | Percentage | |
| 20-30 years | 08 | 16 | 10 | 20 | |
| 30-40 years | 29 | 58 | 27 | 54 | |
| 40-50 years | 11 | 22 | 13 | 26 | |
| 50-60 years | 02 | 4 | 00 | 00 | |
| Total | 50 | 100 | 50 | 100 | |

In both the groups maximum patients are ranged between the age group 30 - 40 yrs. (around 56%).

2. Gender

In this study, all patients are male, so respectively, they are pre-dominant.

Table 9: Occupation wise distribution of Patients

| Occupation | Trial Group | Trial Group | | |
|------------|-------------|-------------|-----------|------------|
| | Frequency | Percentage | Frequency | Percentage |
| Business | 17 | 34 | 19 | 38 |
| Service | 14 | 28 | 14 | 28 |
| Farmer | 15 | 30 | 07 | 14 |
| Driver | 04 | 08 | 03 | 06 |
| Others | 00 | 00 | 07 | 14 |
| Total | 50 | 100 | 50 | 100 |

Both groups had around 38% of patients as Business class.

Besides, the Control group had 28% of Service class and 14% of Farmer, while the Trial group had 28% and 30% of the same.

Table 10: Prakruti wise distribution of Patients

| Prakruti | Trial Group | | Control Group | |
|-------------|-------------|------------|---------------|------------|
| | Frequency | Percentage | Frequency | Percentage |
| Vata-pitta | 23 | 46 | 18 | 36 |
| Vata-kapha | 02 | 04 | 07 | 14 |
| Pitta-vata | 12 | 24 | 10 | 20 |
| Pitta-kapha | 03 | 06 | 04 | 08 |
| Kapha-vata | 06 | 12 | 04 | 08 |
| Kapha-pitta | 02 | 04 | 04 | 08 |
| Pittaj | 02 | 04 | 02 | 04 |
| Kaphaj | 00 | 00 | 01 | 02 |
| Total | 50 | 100 | 50 | 100 |

Above diagram shows that, around majority of patients were of *Vata-pitta prakruti* (45%) followed by *Pitta-kapha* aprrox. 22%.

Table 11: Incidence of Type of Alcohol

| Туре | Trail Group | | Control Group | | |
|----------------|-------------|----|---------------|----|--|
| | No. of Pt | % | No. of Pt | % | |
| Country liquor | 0 | 0 | 10 | 20 | |
| Beer | 10 | 20 | 5 | 10 | |
| Whisky | 30 | 60 | 30 | 60 | |
| Rum | 0 | 0 | 5 | 10 | |
| Combination | 10 | 20 | 0 | 0 | |

Table 12: Incidence of Quantity of Alcohol

| Quantity/Day | Trial Group | | Control Group | |
|--------------|-------------|----|---------------|----|
| (ml) | No. of Pt. | % | No. of Pt. | % |
| 180-360 | 5 | 10 | 6 | 12 |
| 360-540 | 5 | 10 | 12 | 24 |
| 540-720 | 15 | 30 | 2 | 04 |
| 720 & Above | 25 | 50 | 30 | 60 |

Table 13: Incidence of Frequency of Alcohol

| Frequency/ Day | Trial Group | Trial Group | | |
|----------------|-------------|-------------|------------|----|
| | No. of Pt. | % | No. of Pt. | % |
| Once/Day | 3 | 6 | 3 | 6 |
| Twice/Day | 12 | 24 | 3 | 6 |
| Thrice/Day | 5 | 10 | 12 | 24 |
| >3 times/Day | 30 | 60 | 32 | 64 |

Table 14: Duration of Alcohol

| Duration | Trial Group | Trial Group | | Control Group | |
|----------|-------------|-------------|-----------|---------------|--|
| (Years) | No. of Pt | % | No. of Pt | % | |
| 1-5 | 5 | 10 | 5 | 10 | |
| 6-10 | 15 | 30 | 13 | 36 | |
| 11-15 | 25 | 50 | 22 | 44 | |
| 16-20 | 5 | 10 | 5 | 10 | |

Table 15: Incidence of Dilution of Alcohol

| Type | Trial Group | Trial Group | | Control Group | |
|-----------|-------------|-------------|-----------|---------------|--|
| | No. of Pt | % | No. of Pt | % | |
| Diluted | 35 | 70 | 38 | 76 | |
| Undiluted | 15 | 30 | 12 | 24 | |

Table 16: Incidence of Food with Alcohol

| Туре | Trial Group | 捷 8 9集 | Control Group | |
|--------------|-------------|----------|---------------|----|
| | No. of Pt | % | No. of Pt | % |
| With Food | 30 | 60 | 35 | 70 |
| Without Food | 20 | 40 SHDHA | 15 | 30 |

Table 17: Incidence of Food after Alcohol

| Food | Trial Group | Trial Group | | Control Group | |
|-------|-------------|-------------|-----------|---------------|--|
| | No. of Pt | % | No. of Pt | % | |
| Veg | 5 | 10 | 5 | 10 | |
| Mixed | 45 | 90 | 45 | 70 | |

Table 18: Incidence of Other Habits

| Туре | Trial Group | | Control Group | |
|-------------|-------------|----|---------------|----|
| | No. of Pt | % | No. of Pt | % |
| Smoking | 10 | 20 | 7 | 14 |
| Tobacco | 15 | 30 | 13 | 26 |
| Gutakha | 5 | 10 | 8 | 16 |
| Combination | 15 | 30 | 17 | 34 |
| Other | 5 | 10 | 5 | 10 |

Table 19: Incidence of Dosha Dushti

| Dosha | Trial Group | Trial Group | | |
|----------|-------------|-------------|-----------|----|
| | No. of Pt | % | No. of Pt | % |
| Vata | 10 | 20 | 7 | 14 |
| Pitta | 25 | 50 | 30 | 60 |
| Kapha | 10 | 20 | 8 | 16 |
| Tridosha | 5 | 10 | 5 | 10 |

Table 20: . Incidence of Sroto-Dushti

| Srotas | Trial Group | | Control Group | |
|---------|-------------|----|---------------|----|
| | No. of Pt | % | No. of Pt | % |
| Manovah | 35 | 70 | 15 | 30 |

| Pranvah | 8 | 16 | 20 | 40 |
|-----------|----|-----|----|----|
| Udakvah | 5 | 10 | 10 | 20 |
| Annavah | 50 | 100 | 25 | 50 |
| Rasavah | 42 | 84 | 23 | 46 |
| Raktavah | 5 | 10 | 10 | 20 |
| Mansvah | 3 | 6 | 10 | 20 |
| Medovah | 7 | 14 | 22 | 44 |
| Asthivah | 3 | 6 | 8 | 16 |
| Majjavah | 15 | 30 | 35 | 70 |
| Shukravah | 0 | 0 | 0 | 0 |
| Mutravah | 10 | 20 | 25 | 50 |
| Purishvah | 17 | 34 | 35 | 70 |

Physiological Symptoms

1. Chhardi

The *Lakshana Chhardi* was alleviated from a Grade 2 to Grade 0 in the Trial group as compared to the Control group. Trial group showed complete reduction.

2. Aruchi

The *Lakshana Aruchi* was alleviated from a Grade 2 to Grade 0 in the Trial group as compared to the Control group. Trial group showed complete reduction. Control showed no changes.

3. Hrullas

The *Lakshana Hrullas* was alleviated from a Grade 2 to Grade 0 in the Trial group as compared to the Control group. Trial group showed complete reduction, while Control group only reduced by Grade1.

4. Tandra

The *Lakshana Tandra* was alleviated from a Grade 2 to Grade 0 in the Trial group as compared to the Control group. Trial group showed complete reduction, while Control group showed no changes.

5. Staimitya

The *Lakshana Staimitya* was not found in both the groups, Hence both the groups showed Grade 0.

6. Gaurava

The *Lakshana Gaurava* was not so significantly found in both the groups, Hence both the groups showed Grade 0.

7. Hikka

The *Lakshana Hikka* was not so significantly found in both the groups, Hence both the groups showed Grade 0.

8. Shwasa

The *Lakshana Shwasa* was not so significantly found in both the groups, Hence both the groups showed Grade 0.

9. Kasa

The *Lakshana Kasa* was not so significantly found in both the groups, Hence both the groups showed Grade 0.

10. Pralap

The *Lakshana Pralap* was not so significantly found in both the groups, Hence both the groups showed Grade 0.

11. Shirakampa

The *Lakshana Shirakampa* was not so significantly found in both the groups, Hence both the groups showed Grade 0.

12. Parshwashool

The *Lakshana Parshwashool* was not so significantly found in both the groups, Hence both the groups showed Grade 0.

13. Nidranasha

The $Lakshana\ Nidranasha$ was not so significantly found in both the groups, Hence both the groups showed Grade 0

14. Trishna

The *Lakshana Trishna* was not so significantly found in both the groups, Hence both the groups showed Grade 0.

15. Daha

The *Lakshana Daha* was not so significantly found in both the groups, Hence both the groups showed Grade 0.

16. Jwara

The *Lakshana Jwara* was not so significantly found in both the groups, Hence both the groups showed Grade 0.

17. Daurbalya

The *Lakshana Daurbalya* was alleviated from a greater severity to Grade 0 in the Trial group as compared to the Control group. Trial group showed complete reduction, while Control group showed no changes.

18. Murchha

The *Lakshana Murchha* was alleviated from a greater severity to Grade 0 in the Trial group as compared to the Control group. Trial group showed complete reduction, while Control group showed reduction by Grade1.

19. Atisweda

The *Lakshana Atisweda* was not so significantly found in both the groups, Hence both the groups showed Grade 0.

20. Agnimandya

The *Lakshana Agnimandya* was alleviated from a greater severity to Grade 0 in the Trial group as compared to the Control group. Trial group showed complete reduction, while Control group showed reduction by Grade1.

Psychological Symptoms

1. Craving

The Symptom Craving was alleviated from a greater severity to Grade 1.5 in the Trial group as compared to the Control group. Trial group showed almost complete reduction, while Control group showed reduction by Grade 2.

2. Depression

The Symptom Depression was alleviated from a greater severity to Grade 1.5 in the Trial group as compared to the Control group. Trial group showed almost complete reduction, while Control group showed reduction by Grade 2.

3. Irritability

The Symptom Irritability was alleviated from a greater severity to Grade 1.5 in the Trial group as compared to the Control group. Trial group showed almost complete reduction, while Control group showed reduction by Grade 2.

4. Insomnia

The Symptom Insomnia was alleviated from a greater severity to Grade 2 in the Trial group as compared to the Control group. Both groups showed same results.

5. Restlessness

The Symptom Irritability was alleviated from a greater severity to Grade 1.5 in the Trial group as compared to the Control group. Trial group showed almost complete reduction, while Control group showed reduction by Grade 2.

6. Anxiety

The Symptom Insomnia was alleviated from a greater severity to Grade 1.5 in the Trial group as compared to the Control group. Both groups showed same results.

7. Impaired Concentration

The Symptom Impaired Concentration was alleviated from a greater severity to Grade 1.5 in both the groups.

8. Disinclination to Work

The Symptom Disinclination to Work was alleviated from a greater severity to Grade 1.5 in the Trial group as compared to the Control group.

Objective Parameters

1. Hemoglobin (Hb)

The objective parameter of Hb recorded a better result in the Trial group to a minimal result in the Control group.

2. Bilirubin (Total)

The objective parameter of Bilirubin (Total) recorded a better result in the Control group as compared to the Trial group.

3. Bilirubin (Direct)

The objective parameter of Bilirubin (Direct) recorded a better result in the Control group as compared to the Trial group.

4. Bilirubin (Indirect)

The objective parameter of Bilirubin (Direct) recorded a better result in the Control group as compared to the Trial group. Trial group showed no changes.

5. SGOT

The objective parameter of SGOT recorded a better result in the Trial group compared to the Control group.

6. SGPT

The objective parameter of SGPT recorded a better result in the Trial group compared to the Control group.

7. Alkaline Phosphate

The objective parameter of Alkaline Phosphate recorded a better result in the Trial group compared to the Control group.

DISCUSSION

In India, day by day, increasing prevalence rate of alcohol related disorders is being noted. May be attracted towards the western culture or the effect of the media has contributed to this. Irrespective of cultural, geographical, educational, and economic differences, an increasing rate of consumption of alcohol is a major problem with extensive legal, social, moral, ethical consequences all over the world. Purposeless and repeated use of alcohol produces a gradual, physical and moral deterioration of the individual and leads to crimes or perversions. This alcohol abuse interferes with the health, social relationships, economic stability, which have effects further in other areas in terms of illness, disability, decreased productivity, accidents, crimes, family disorientation, economic and psychological hardships, and lastly death in all classes of the society.

An increase in the severity of the withdrawal state, other factors like nutritional deficiency, poor physical health, other systemic pathologies, lack of emotional and family support, etc are responsible. There is no specific treatment modality available in conventional science for detoxifying the effects of alcohol. On the contrary, Ayurved mentions many drugs for such detoxification. That is why this study entitled 'A Clinical study to assess the efficacy of Mrudweekadi Kashaya and Kalyanka Ghrita in Madatyaya was carried out. The drug selected was Mrudweekadi Kashaya which is Balya, Rasayana, Agni deepana and Srotoshodhaka. Vagbhatacharva quotes the utility of Kalvanaka ahrita in Bhutgraha, Unmad, Apasmar, Daivopahatcetasi etc. Which indicates its action on Manovahastrotas by empowering it. In Madatyaya due to Madya along with *Agni dhushti, Srotodushti* is also a pathological change. To treat that Mrudweekadi Kashaya and Kalyanaka Ghrita was selected.

Age

In this study the control group and trial group showed maximum 56% of patients belonging to 30 - 40 years of age group and the prevalence goes down in elderly people.

Occupation

This study reveals that prevalence of *Madatyaya* is more in Business and Service category people with 38 % in control group and 34 % of Business in Trial group, then in Service were 28% in both Trial group and Control group, and rest were Farmers, Drivers and others including retired and unemployed etc. This may be because of stress of business and office, friends company and financial soundness.

Prakruti

In control (36%) as well as in trial group (46%) maximum patients were of *Vata-Pitta Prakruti*. The patients of *Pitta-Vata Prakruti* occupy second place having 20% in Control and 24% in Trial group.

Type of Alcohol

This study shown maximum people of both the Groups were addicted to Whisky (60 %) but in Trial group people taking Beer and combination of more than one type also occurred more (40%). This may be because of cost, the Whisky being cheaper and produces maximum kick hence maximum people use it and local beverages are still in use in spite of ban over it.

Quantity of Alcohol Consumption

This study showed maximum people of control (60%) and trial group (50%) takes 720ml & more alcohol per day.

Frequency of Alcohol consumption

64% peoples of control and 60% of trial group consumes alcohol more than 3 times per day.

Duration of Alcohol Consumption

44% of people in control group and 50% of peoples in trial group consuming alcohol since 11-15 years. Peoples consuming alcohol since 6-10 years are 36% in control group and 30% in trial group whereas peoples consuming alcohol above 16 years are 10% in both the groups.

Dilution of Alcohol Consumption

This study reveals that 76% people of control and 70 % of trial group consumes alcohol in diluted form. For dilution they may prefer soda, carbonated cold drinks or only water.

Food intake with Alcohol consumption:

70% people of control group and 60% of trial group consumes alcohol with food.

Food intake after Alcohol consumption

This study shows that maximum no. of people i.e. 90% in both the Groups take mixed type of food after consumption of alcohol. Thus aggravating the *Dosha & Dushti*.

Other Addiction

26% of peoples in control and 30% in trial group have a habit of tobacco chewing. But large number of patients i.e. 34% in control group and 30% in trial group have habit of either 2 or more than 2 of the following addictions i.e. *Gutakha*, smoking and tobacco called combination type of habit. These addictions are indicative of *Rajoguna Vridhi* of *Mana*.

Dosha Dushti

This study reveals that in majority of people (55%) *Pitta dosha* get affected largely, whereas *Vata* and *Kapha Dosha* were found to be vitiated to a lesser extent.

Sroto-Dushti

According to this study, *Annavaha* and *Rasavaha* srotasa get largely affected in alcoholics of both groups but it also reveals that *Manovaha*, *Majjavaha* and *Purishvaha* srotasa are the next mostly affected srotasa.

I. Effect on Physiological Symptoms

Mrudweekadi Kashaya and Kalyanaka Ghrita gives relief in the subjective symptoms as well as in objective criteria like Liver Function test of patients of Madatyaya. The result of this study showed there was

significant improvement in the trial group compared to control group.

A. Effect in Control Group

In control group, up to some extent, there is significant reduction in the severity of *Chardi, Agnimandya, Aruchi, Trishna and Pralap* at day 28. This can be due to-

- 1) Complete abstinence of alcohol intake i.e. *Nidanparivarjan*.
- 2) Balanced diet/regimen is followed.
- 3) Supplemented by yoga, meditation and counseling.

B) Effect in Trial Group

In the trial group out of 20 symptoms two symptoms showed highly significant relief, 9 symptoms shows significant relief and 3 symptoms shows no significant reduction in the severity.

1. Chhardi-[S]

In control group at Day-0, 30% of patients were of Grade-4 which was decreased to 20 % by Day 28 in 30% patients. However in the trial group 60% patients of Grade 3 showed a reduction of 75% by the day 21. This indicates that the medication alleviated the greater severity of the *Lakshana* within a lesser time period (3 weeks early). This is due to the *Deepan pachan & Vatanuloman* action of *Mrudweekadi Kashaya*.

2. Aruchi- [.S.]

Considering the *Aruchi Lakshana*, of the control group 30% of patients showed reduction in symptom up to 25% by 28th day. However in the trial group 50% patients showed relief of 75% in the symptom by the 28th day. This indicates that the medication alleviated a greater severity of the *Lakshana* which may be due to *Deepana guna* of *Mrudweekadi Kashaya*. Also drugs like *Triphala*, *Haridra* and *Dadima of Kalyanaka Ghrita* are responsible for this.

3. Hrullas-[S]

In the *Hrullas Lakshana* of the control group minimum number of patients were in grade 3 (50%) that was reduced in 25% of patients by Day- 35. However in the trial group 75% patients showed grade 3 severities and that was altered to grade 1 by the day 21th in 100% patients.

This indicates that the medicine alleviated the same severity of the *Lakshana* within a lesser time period. To relieve the *Hrullas*, ingredient like *Musta*, *Pippali*, *Ushira in Mrudweekadi Kashaya* having *Pittaghna* property may have proved useful.

4. Tandra

In control group at Day-0, 20% of patients were of Grade-2 which was reduced by Day 28 in 10% patients. However in the trial group 30% patients of Grade 2 showed a reduction of 100% by the day 28. This indicates that the medication reduced the same severity of the Lakshana within a lesser time period.

5. Gaurav :[S]

Considering the *Gaurav Lakshana*, in control group at Day-0, 30% of patients were of Grade-2 which was reduced within Day 28 in 10% patients. However in

the trial group 25% patients of Grade 2 showed a reduction of 100% by the day 21. This indicates that the medicine reduced the severity of *Gaurav* within a lesser time period. In case of *Gaurava*, *Kaphaghna* and *Kledaghna guna* of drug like *Pippali*, *Musta* are responsible. Also Drugs like *Triphala*, *Tagar*, *Kustha* and *Dadima* of *Kalyanaka Ghrita* are responsible.

6. Kasa and Daha

Considering the *Kasa* and *Daha Lakshana*, in control group at Day-0, 30% of patients were of Grade-2 which showed no reduction till day 49. However in the trial group 40% patients of Grade 2 showed a reduction of 100% by the day 21. This indicates that the medicine reduced the severity of *Kasa* and *Daha* within a lesser time period. In case of *Kasa*, *Kaphaghna* and *Kledaghna guna* of drug Pippali is responsible. In case of *Daha*, *Kaphapittaghna* of drug *Chandana* is responsible. Also drug *Brihati* and *Talispatra* of *Kalyanaka Ghrita* for *Kasahara* and drug like *Chandan*, *Nilkamal*, *Ela* and *Brihat Ela* for *Dahaprashaman* are responsible.

7. Daurbalya-[H.S]

In control group at Day-0, 70% of patients were of Grade-3 which was reduced by Day 28 in 60% patients. However in the trial group 60% patients of Grade 3 showed a reduction of 100% by the day 21. This indicates that the medication alleviated the same severity of the aim within a lesser time period i.e. 1 week early. This can be due to the *Rasayan* karma of *Draksha* by causing *Dhatvagnideepana* due to its *Madhur rasa* and *Sheeta veerya* and by expelling *Dosha* accumulated in *Srotasa*. The *Balya*, *Brunhan* actions of *Kharjura* also helps to reduce *Daurbalya*. Also *Kalyanaka Ghrita's* drug like *Amalaki*, *Haritaki*, *Dadima* and *Goghrita* are also responsible.

8. Nidranash

The control group 50% patients showed Grade-3 severity that was reduced by Day-28 in 20%. However, in the Trial group 35% patients of Grade 3 showed a relief of 100% by the day 14. In *Nidranash* the same severity of the *Lakshna* was achieved within a lesser time period i.e. 2 weeks early.

9. Shirokampa and Murchha

In control group at Day-0, 20% of patients were of Grade-2 which was reduced by Day 28 in 10% patients. However in the trial group 40% patients of Grade 2 showed a reduction of 100% by the day 28. This indicates that the medication reduced the same severity of the *Lakshana* within a lesser time period (1 week early).

II. Changes in Psychological Symptoms

A) Effect on Control Group

In control group, up to some extent, there is significant reduction in the severity of Anxiety, Craving, Insomnia, Impaired concentration and Disinclination to work at day 35. This can be due to-

- 1) Complete abstinence of alcohol intake i.e. *Nidanparivarjan*.
- 2) Balanced diet/regimen is followed.

- 3) Supplemented by yoga, meditation and counseling.
- 4) Symptomatic treatment received if necessary.

B) Effect on Trial Group

In the trial group out of 8 symptoms all the symptoms shows significant reduction in the severity. This may be due to ingredients of *Kalyanka Ghrita* having pharmacological action on Psychological Symptoms as they are antioxidents, Rejuvenating, Immunomodulatory, Digestive, Antiacetylcholine and anticholinesterase in properties. Also, drugs like *Draksha, Kharjura, Chandana, Sariva* and *Ushira* of *Mrudweekadi Kashaya* are responsible.

III. Changes in Pathological Tests

Considering the Pathological investigations, we conducted Haemoglobin and Liver Function Tests which includes Total Billirubin, Direct Billirubin, Indirect Billirubin, SGPT, SGOT, and Serum Alkaline Phosphatase.

A) Effect in control group

Among the above said investigations in Control Group,- there were significant changes in Total Billirubin, Direct Billirubin, Indirect Billirubin, rest showed no significant changes.

B) Effect in trial group

There is highly significant reduction in all the investigations except Billirubin profile.

1) Effect on Hemoglobin percentage

Before the treatment with *Mrudweekadi Kashaya* and *Kalyanaka Ghrita*, mean value of Haemoglobin was 13.2 which became 13.9 after the treatment, showing increase of. 70 in mean value whereas in control group mean difference was 0.20 only. It shows drug was effective and statistically highly significant.

This could be possible due to the ingredients in Mrudweekadi Kashayae specially Draksha, Yashtimadhu, Pippali which are having Rakta prasadana and balya Raktavardhaka, Yakriduttejaka, properties, vriddhihara, Rasayana, Also appetite and metabolism could have been increased due to Deepan karma of Mrudweekadi Kashaya, which directly affects the Hb level in trial group. Most of the ingredients of M K are *Madhur* Rasatamaka, Sheeta Virvatamaka, Vata Pittashamaka and Shonitsthapaka it could be helpful in increasing Haemoglobin. Also drugs like Triphala, Sariva, Haridra, Daruharidra, Manjishtha, Nagkeshar and Dadima of Kalyanak Ghrita are responsible as they are Deepan, Rasayana, Yakrid-pleeha uttejaka.

2) Liver Function Test

Likewise in LFT it showed that the drug was effective and statistically highly significant in the investigations of SGOT, SGPT and Alkaline Phosphate

SGOT

After the treatment, mean value of SGOT (IU/L) was decreased by 12 on the other hand in control group mean difference was decreased by 10 It shows drug was effective and statistically highly significant.

SGPT

After the treatment, mean difference of SGOT (IU/L) was decreased by 12.7 however in control group

decrease in mean difference were 10.4 only. It clearly shows drug was effective and statistically highly significant.

Alkaline Phosphate

After the treatment with *Mrudweekadi Kashaya* and *Kalyanaka Ghrita*, average difference of Alkaline Phosphate (IU/L) was decreased by 33.6. Whereas in control group decrease in difference was 29 only. It implies that drug was effective and statistically highly significant. As *Chandan*, *Yashtimadhu*, *Triphala*, *Sariva*, *Krishna Sariva*, *Vishala*, *Brihat Ela*, *Haridra*, *Manjistha*, *Tagar*, *Priyangu*, *Shalparni*, *Nagkeshar*, *Malati*, *Kamal and Padmaka* possesses *Vishghna* property; *Mrudweekadi Kashaya* and *Kalyanaka Ghrita* could probably detoxify the toxic effects of *Madya* on Liver thus helpful.

CONCLUSION

- Mrudweekadi Kashayam and Kalyanak Ghrita are
 effective in alleviating 7 of the 20 physiological
 symptoms of Daurbalya, Aruchi, Chhardi, Hrullas,
 Shirokampa, Murcha and Nidranasha as also all the 8
 Psychological symptoms namely Craving,
 Depression, Irritability, Insomnia, Restlessness,
 Anxiety, Impaired concentration and Disinclination
 to work showed
- Better reduction of pathological parameters was also noted especially so in Heamoglobin, SGOT, SGPT and Alkaline phosphatase.

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