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CLINICAL STUDY TO EVALUATE EFFECT OF POLYHERBAL COMBINATION: 'WESNIL PLUS' FOR ALCOHOL DE-ADDICTION

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Abstract

Alcoholism, also known as alcohol use disorder, is a condition in which a person has a desire or physical need to consume alcohol, and impaired ability to stop or control alcohol use despite adverse social, occupational, or health consequences." Alcoholism mainly damages important organs like liver, heart and brain. Many psychological illnesses like dementia, anxiety and depression are caused by alcohol addiction. More over Alcoholism poses extra financial burden and affects quality of life. Hence it is important to treat the alcohol dependence to reduce or stop alcohol consumption by the addicted individual. Considering the need of safe medication for alcohol de-addiction, A clinical Trial was conducted on a Poly herbal combination Wesnil Plus to evaluate its effect for alcohol de addiction. Statistically significant improvement was seen on Alcohol withdrawal scale in the treated patients and the craving and frequency of alcohol consumption was significantly reduced.

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Introduction: -

In developing countries like India, alcohol consumption tends to be a major problem. Alcohol consumption among both men and women is higher in rural India than in urban India, the National Family Health Survey-5 (NFHS-5), 2019-21 has found. Overall, 1% of women aged 15 and over drink alcohol, compared to 19% of men in the same age group. This breaks up into 1.6% (rural) and 0.6% (urban) among women, and 19.9% and 16.5% respectively among men.¹

People in developing countries like India tend to attract or get addicted to alcohol consumptions due to various reasons like various socio-cultural practices, lack of awareness of alcohol-related problems among the community, false mass media propaganda about alcohol use, stressful works etc.

Alcohols consumption negatively affects the physical mental health of the addicted person, also it imposes adverse impact on his financial capacities, family and social lives

Alcoholism, also known as alcohol use disorder, is a condition in which a person has a desire or physical need to consume alcohol, even though it has a negative impact on their life.

Hence it is important to treat the alcohol dependence to reduce or stop alcohol consumption by the addicted individual.

Treatment of alcoholism comprises following main aspects²:

- 1) Reduce the craving for alcohol (repel from alcohol) or abstinence
- 2) Treat underlying withdrawal symptoms
- 3) Correction of metabolic derangements occurred due to alcohol.
- 4) Rehabilitations at Alcohol anonymous or behavioral therapies.

Some of the Ayurvedic herbal drugs are effective in treating underlying withdrawal symptoms, some drugs create aversion by inducing nausea, and some drugs help in hepato protection and correct metabolic derangements. A poly herbal combination Wesnil plus which contains drugs having above properties was studied in clinical trial. The formulation Wesnil plus Ayu. Powder contained 1. Ajmoda (*Cariumcopticum*) 2. Madanfal (*Randia Dometorum*) 3. Dhaniya (*Coriandrum sativum*) 4. Lakh (*Lecciferlacca*) 5. Saindhav (*SodilChloridum*) 6. Chyavak (*Pipar Glabra*) 7. Rai (*Brassicaluancean linn.*) 8. Lawang (*Cariophyllus*) 9. Sunth (*Zingiber officinale*) 10. Vacha (*Acorus Calamus*).

The study was conducted in R APodar govt medical college (Ayu), worli and at Jeewanjyoti De-addiction centre Jalgaon. Total 60 patients were enrolled in the present study. In this study 56 patients completed the treatment. 28 patients

46 % showed excellent improvement out of that patients. 18 patients i.e. 30 % showed good improvement. 7 patients i.e. 11 % showed fair improvement
3 patients i.e. 5 % showed poor response or no change.

The craving for alcohol and frequency of alcohol consumption was also reduced significantly in treated patients.

Materials and Methods: -

Before commencing the trial clearance from institutional ethical committee was obtained. (ref. letter no. RAP/IEC/CT/Wesnil plus/2022/6069).

The trial was registered with CTRI (Registration no. CTRI/2022/09/045406).

Recruitment :- The subjects were recruited from
1) OPD of R.A Poda govt. medical college (Ayu) worli,
2) jeevanjyoti Nasha mukti Kendra, Jalgaon

Inclusion and Exclusion criteria for study subjects :-

Inclusion Criteria:-

Males age group > 20 to 70 years, having history of Chronic alcohol consumption for more than 3 years. Patients may or may not be having any of the symptoms of symptoms Alcohol withdrawal including vomiting, nausea, tremors, anxiety, agitation.

Exclusion criteria:-

- Patient is accompanied by the seriously abnormal symptoms in GI, Nervous, Cardio-vascular, Renal, Metabolic, etc.
- Patients with h/o hematemesis, active PR bleeding and hemorrhoids
- Patient who has clinical history of sensitivity of ingredients in Wesnil Plus.
- Patient suffering from uncontrolled DM, HTN, Acute coronary Artery diseases, Asthma & any other major illness.
- Patients on antitubercular and antiretroviral treatment.
- Patient whose heart, liver or kidney function is seriously abnormal.
- Patient who has participated in other clinical trial within two months before starting these trials.

Sample size:

Total 60 patients enrolled 56 completed study

Study procedure

Drug used :Wesnil plus Ayu.Powder

Each 100 gm. Wesnil plus Ayu.powder content formulation

- | | |
|---|---|
| 1. Ajwan (Cariumcopticum) = 1.5 gm | 6. Chyavak (PiparGlabra) = 1.5 gm |
| 2. Madanfal (Randia Domatorum) = 1.0 gm | 7. Rai (Brassicaluancean linn.) = 30 gm |
| 3. Dhaniya(Coriandrum sativum) = 1.5 gm | 8. Lawang (Cariophyllus) = 1.5 gm |
| 4. Lakh (Lecciferlacca) = 30 gm | 9.Sunth (Zingiber officinale) = 1.5 gm |
| 5. Saindhav (SodilChloridum) = 1.5 gm | 10.Vacha (AcorusCalamus) = 30 gm |

Dosage schedule :-

The Wesnil Plus was provided to the patient free of cost for period of one month

dose and frequency :

WesnilPlus Ayurvedic Powder of 1 gm at H.S. with milk

Patient recruitment :

Patients addicted for alcohol (not less than 3 years) were identified at OPD at . R.A.Podargovt.medical college (Ayu) Worli

Institutional tie up was done with alcohol anonymous organization: Jeewanjyoti Nasha Mukti Kendra Jalgaon, from where pts were recruited.

The voluntary informed contents was taken prior to inclusion criteria assessment, demographic data, history, physical & systemic examination, blood pressure (SBP / DBP) , baseline assessment was done.

1) Patients' alcohol consumption:

2) Frequency of alcohol consumption: is recorded as average frequency of alcohol consumed –days per week.

3) Patients were assessed on 9 point Short Alcohol withdrawal assessment scale³ clinically to assess severity alcohol withdrawal symptoms as: (Subjective assessment)

Alcohol short assessment scale:**Criteria**

Following symptoms were assessed in patients

Anxious, Feeling confused, Restless, Miserable, Memory problems, Tremors, Palpitations

Sleep disturbance or Insomnia, Sweating.

Each symptom was scored as 0 to 3: Score 0: None Score 1: Mild Score 2: Moderate ,

Score 3: Severe and total of scored points is done to get final score which was then interpreted as Score <12: Mild Alcohol Withdrawal

Score 12 or more: Moderate to severe Alcohol Withdrawal

The frequency of alcohol consumption was measures as number of consumptions per week and recorded accordingly in CRF (case record form)

Investigational assessment: CBC, LFT, KFT , BSL (F and PP), was done at starting and at the end of study. Sr.Electrolytes and ECG were done if indicated .

Observations:-

Total 60 patients were enrolled in the present study.

In this study 56 patients completed the treatment and 1 patient was withdrawn from the study.3 patients did not give the regular follow up so they were considered as drop out and new patients were recruited in their place.

Age wise distribution of the patients:

Out of 60 patients 28 patients were in age group of 20 to 40 yrs. 32 patients were from 40 to 60.

Symptom wise relief in patients:

1. Anxiety:

This symptom was present in 47 out of 56 patients i.e 78.56% before treatment.

And after treatment the symptom persisted in 28 patients i.e. 50 % but in milder form

Mean score for anxiety is 2.017 and after treatment it became 0.7368

2. Restlessness:

This symptom was present in 44 out of 56 patients i.e 83.92% before treatment.

And after treatment the symptom persisted in 26 patients i.e. 46.42 % but in milder form

Mean score for restlessness is 1.9333 and after treatment it became 0.7719

3. Miserable

This symptom was present in 27 out of 56 patients i.e 48.21% before treatment.

And after treatment the symptom persisted in 18 patients i.e. 32.14 % but in milder form

Mean score for miserable is 1.250 and after treatment it became 0.5614

4. Confusion:

This symptom was present in 30 out of 56 patients i.e 53.57% before treatment.

And after treatment the symptom persisted in 16 patients i.e. 28.57 % but in milder form

Mean score for confusion is 1.267 and after treatment it became 0.5439

5. Memory problem:

This symptom was present in 32 out of 56 patients i.e 57.14% before treatment.

And after treatment the symptom persisted in 18 patients i.e. 32.14 % but in milder form

Mean score for memory problem is 1.167 and after treatment it became 0.4271

6. Tremors

This symptom was present in 42 out of 56 patients i.e 75% before treatment.

And after treatment the symptom persisted in 19 patients i.e. 33.92 % but in milder form

Mean score for tremors is 1.700 and after treatment it became 0.5431

7. Palpitation:

This symptom was present in 32 out of 56 patients i.e 57.14% before treatment.

And after treatment the symptom persisted in 13 patients i.e. 23.21 % but in milder form

Mean score for palpitation is 1.555 and after treatment it became 0.8459

8) Sweating :

This symptom was present in 38 out of 56 patients i.e 67.85% before treatment.

And after treatment the symptom persisted in 16 patients i.e. 28.57 % but in milder form

Mean score for sweating is 1.300 and after treatment it became 0.3509

9) Insomnia:

This symptom was present in 42 out of 56 patients i.e 75% before treatment.

And after treatment the symptom persisted in 22 patients i.e. 39.28 % but in milder form

Mean score for insomnia is 1.533 and after treatment it became 0.4737.

10) Total score for alcohol withdrawal scale:

The sum of grading for each symptom was recorded as total score on alcohol withdrawal scale for each patient and was then assessed statistically.

The mean score on alcohol withdrawal scale before treatment was 13.333. After treatment this score was reduced upto 4.649.

Frequency of consumption of alcohol per week was also recorded before and after treatment. It was ranging from maximum 7 days per week to 1 w per day with the mean of 4.8 before treatment.

| Assessment criteria | Mean before treatment | Mean after treatment | Std deviation Before | Std deviation after | P value | Significant/ Insignificant |
|----------------------------------|-----------------------|----------------------|----------------------|---------------------|---------|----------------------------|
| Anxiety | 2.052 | 0.7368 | 1.343 | 0.8768 | <0.0001 | Significant |
| Restlessness | 1.933 | 0.7719 | 1.494 | 0.9823 | <0.0001 | Significant |
| Miserable | 1.250 | 0.5614 | 1.48 | 0.866 | 0.0148 | Significant |
| Confusion | 1.267 | 0.5439 | 1.436 | 1.013 | 0.0089 | Significant |
| Memory problem | 1.167 | 0.211 | 1.330 | 0.7058 | 0.0051 | Significant |
| Tremors | 1.700 | 0.5439 | 1.453 | 0.9462 | <0.0001 | Significant |
| Palpitation | 1.233 | 0.3929 | 1.555 | 0.8459 | 0.0011 | Significant |
| Sweating | 1.300 | 0.3509 | 1.212 | 0.6121 | <0.0001 | Significant |
| Insomnia | 1.533 | 0.4737 | 1.214 | 0.6841 | 0.0012 | Significant |
| Total score | 13.33 | 4.664 | 8.9850 | 6.4261 | <0.0001 | Significant |
| Frequency of alcohol consumption | 4.893 | 0.6964 | 1.875 | 0.6006 | <0.0001 | Significant |

Table 2:-Statistical analysis of observations.

After treatment the mean of frequency of alcohol consumption was 0.68.

The observations are summarized in percentage as:

| Sr.no. | Sign / symptom | Present in no. of patients before treatment | Present in no. of patients Before Treatment percentage | Present in no. of patient after treatment | Present in no. of patients after treatment Percentage |
|--------|-----------------|---|--|---|---|
| 1 | Anxiety | 47 | 83.92% | 28 | 50% |
| 2 | Restlessness | 44 | 78.56% | 26 | 46.42% |
| 3 | Miserable | 27 | 48.21% | 18 | 32.14% |
| 4 | Confusion | 30 | 53.57% | 16 | 28.57% |
| 5 | Memory problems | 32 | 57.14% | 18 | 32.14% |
| 6 | Tremors | 42 | 75% | 19 | 33.92% |
| 7 | Palpitations | 32 | 57.14% | 13 | 23.21% |
| 8 | Sweating | 38 | 67.85% | 16 | 28.57% |
| 9 | Insomnia | 42 | 75% | 22 | 39.28% |

Table 1:- Percentage change in symptoms of Alcohol withdrawal scale.

Laboratorial findings:

To assess safety of drug laboratorial findings like L F T and R F T along with CBC were done that did not show any gross alterations before and after treatment.

Drop out patients:

3 patients were dropped out from the study because they did not remained compliant with the dosage schedule and follow up schedule

Adverse event:

1 patient developed adverse event in the form of mild P R bleeding which was diagnosed as acute fissure in ano and was treated successfully and followed till resolution.

Statistical analysis

To assess the treatment outcomes the data procured from the trial was analyzed with statistical tests. As the alcohol withdrawal scale is a gradation scale, the data obtained is non parametric normally distributed data. And hence Willcoxon signed rank test was applied and P value is observed. $p < 0.005$ was considered statistically significant.

Probable mode of action:

The drug Wesnil plus contains 10 herbal drugs like madanfal, vacha, sarshap, lavan, shunthi, ajmodaa, laksha, dhanyak, chawyaksaindhav. These drugs are predominantly katutiktarasatmakkatuveerya and katuwipaki and ushnagunaatmak they have good digestive property and help in detoxification and improving metabolism⁴⁻¹³. and most of the drugs like madanfhal, vacha, saindhav, chyawakmaily have gastric irritant property which can be responsible for creating aversion against alcohol reducing craving for alcohol consumption and hence this formulation acts to repel the alcohol craving.

Also, Ajmoda, Vacha like drugs in formulation have medhya and some anticonvulsive property and hence neurological symptoms in mild to moderate range might have been reduced.

In overall trial the drug was well accepted and tolerated by the patients during the period of 1 month, and the craving for alcohol was reduced during the one month of trial period.

Conclusion: -

From the above observations and discussions it can be concluded that in the clinical study entitled **A Prospective, Open label, Clinical Study to assess the safety and efficacy of Wesnil Plus in alcohol de-addiction.**

The drug Wesnil plus is effective in reducing alcohol addiction by repelling the use of alcohol, Also it helps to control withdrawal symptoms if they are present in mild to moderate scale.

The drug wesnilplus is well tolerated without any serious side effects on clinical and investigational criteria. That means drug can be safely given in patients with normal liver and renal function.

Scope of study:

To evaluate long term results of drug the study can be performed on mass scale and the follow up can be done for longer duration for 6 months or so.

Sponsorer:

The study was sponsored by

Shri. Saptshrungi Nivasini Ayurvedic Company
Gate No. 116, Plot No. 28, Bajrang Housing Society,
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Intrests of conflicts :none

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