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CODEN: IJRSFP (USA)

International Journal of Recent Scientific Research Vol. 10, Issue, 05(A), pp. 32178-32181, May, 2019 International Journal of Recent Scientific Re*r*earch

DOI: 10.24327/IJRSR

Research Article

EFFECT OF Ajamoda Arka IN ALCOHOL WITHDRAWAL SYNDROME- A RANDOMIZED CONTROLLED TRIAL

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DOI: http://dx.doi.org/10.24327/ijrsr.2019.1005.3413

ARTICLE INFO	ABSTRACT
<i>Article History:</i> Received 4 th February, 2019 Received in revised form 25 th March, 2019 Accepted 23 rd April, 2019 Published online 28 th May, 2019	Background and objectives: Alcohol abuse affects the health, social relationship and economic stability of the individual. When a chronic alcoholic tries to reduce or completely stop the alcohol intake then a cluster of symptoms manifests termed as Alcohol withdrawal syndrome (AWS). Treatment has to be started from this stage itself so as to keep aside possible complications. Previous studies concluded that Ashtāngalavanayukta takra which isVāta Kapha hara and indicated for Kaphaja madātyaya is effective in reducing the signs and symptoms of AWS. Hence Ashtāngalavanayukta takra was selected as control drug. Ajamoda arka is conventionally in use with
Key Words:	results for the management of AWS was selected as the trial drug. Methodology: 20 Participants each of age 20-50 years satisfying the inclusion criteria were selected
Alcohol withdrawal syndrome, Madātyayam, Ajamoda arka, Ashtāngalavanayukta takra	randomly into two groups using software generated random numbers. The clinical study was conducted with trial drug at a dose of 20ml with 10ml water 1 hour after food twice daily for 7 days and control drug 6gm along with 250 ml of takra twice daily for 7 days assessment were done before treatment, on 4th day, on 7th day and after follow up using CIWA-Ar scale. Result: By assessing with CIWA- Ar scale Ajamoda arka and Ashtāngalavanayukta takra were found as statistically significant at a level of p<0.001 in reducing the signs and symptoms of AWS. On comparing trial with control group, it was found to be statistically insignificant. That indicates both groups are having not much difference in efficacy.

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INTRODUCTION

In India prevalence of alcohol abuse among women is less than 5%¹ but in males it is almost 16.8%.² The timely management is very much essential so as to prevent serious complications such as seizures and even delirium tremens. Modern management of alcoholism reported to have several limitations in their effectiveness as per published studies. No successful treatment for alcohol craving, relapse and to prevent withdrawal sensitization is available. Detoxification is always with risk including anxiety and seizures at any time and considered as not ethical by many³.

Alcohol dependency is a cluster of physiological, behavioural, and cognitive phenomena in which the use of a substance or a class of substances takes on a much higher priority for a given individual than other behaviours that once had greater value⁴. Alcohol withdrawal refers to symptoms that may occur when a person who has been drinking too much alcohol on a regular basis suddenly stops drinking alcohol⁵. Nausea and vomiting, tremor, paroxysmal sweats, anxiety, agitation, tactile disturbances, auditory disturbances, visual disturbances, head

ache, fullness in head, orientation and clouding of sensorium, delirium tremens and withdrawal seizures are the presentation of AWS. Intervention, detoxification and rehabilitation are the three essential steps of management.⁶

Madva or alcohol and its use and abuse with management protocols are explained in Avurvedic texts with due importance. *Madva* is possessing characteristics similar to *visa* and opposite to that of ojas, the immune protective factor mentioned in Indian medicine. So, if it is not administered in a proper or regulated manner, then acts like visa ie. a slow acting poison. Madātyaya is of four types based on the involvement of the three doshas as Vāta, Pitta, Kapha and Sannipata⁷. It is a disease involving tridosās as well as the doshas of manas, the *rajas* and the *tamas*^{δ}. So, treatment should be aimed at the most predominant dosa, based on the presentation. If all the dosas aggravated equally then, Kapha should be pacified first followed by Pitta and Vāta in a respective manner. Ācarya Kasyapa has been explained three stages of alcoholism, namely pānātyayam, pānavibhrama and pānāpakramam. Here pānāpakramam is the resultant clinical condition of the sudden stoppage of alcohol⁹.

Need and significance of the study

Previous studies concluded that ayurvedic drugs are capable of managing AWS issues. Ajamoda arka is reported as clinically effective but no trials have been conducted so far in this regard. It seems also cost effective and was compared with the studied drug. the *Aştāngalavaņayuktatakra*.

METHODOLOGY

Aim

To provide a better and cost-effective management for Alcohol withdrawal syndrome.

Objectives

- To assess the efficacy of Ajamoda arka in Alcohol withdrawal syndrome.
- To compare the efficacy of *Ajamoda arka* with *Astāngalavaņayukta takra* in Alcohol withdrawal syndrome.

MATERIALS AND METHODS

Materials

Medicine

A) Group 1: Trial: *Ajamoda arka¹⁰*:
B) Group 2: Control: *Aştāngalavaņayuktatakra¹¹*Diagnostic tool: CIWA-Ar scale (Clinical Institute Withdrawal Assessment of Alcohol scale, Revised)¹²

Methods

Study design	: Randomized controlled trial.					
Settings :	Manassān	ti IP	D of	VPSV	Ayurveda	
College Hospital, Kottakkal.						
Duration :	18 months					
Sample size	: 2	20 (Sir	nple rai	ndom san	npling)	

Randomization was done as per the random number table generated on 14/08/2017

The protocol was approved by the Research committee and Institutional ethics committee (IEC). no. IEC/Doc/11/2016, dated 18/4/2016.

Diagnostic Criteria

DSM-IV-TR diagnostic criteria for Alcohol withdrawal syndrome¹³

Inclusion Criteria

Those subjects between 20-50 years with no discrimination of gender, caste, religion and economic status satisfying DSM-IV criteria and last alcohol intake within 24-48 hours preceding the initiation of the therapy with a given informed consent were included.

Exclusion Criteria

Subjects with systemic and metabolic disorders, severe gastritis, co-morbid psychiatric disorders, and other psychoactive substance abuse excluding Nicotine, withdrawal seizures and delirium tremens and currently undergoing any treatment for alcoholism were excluded.

Assessment Criteria

Assessment was done on 0th, 4th, 7th and follow up on 10th day.

Drug Review

Ajamoda arka is explained under arka preparations in Arkaprakāşa¹⁴ and Aştāngalavana¹¹ in madātyaya cikitsa of vaghbata. Both the trial and control drugs are having Vata Kapha hara property. Both these drugs are generally possessing $d\bar{p}ana$, $p\bar{a}cana$ and anulomana properties. Kostharogās are indicated in Ajamoda arka¹⁰ where as in Aştāngalavana it has been mentioned as the best among the srotorodha rectifying drugs for madatyaya.

Observations and analysis

The effect of therapy with in groups was tested with Friedman Test, followed by Wilcoxon Signed Ranks Test for pairwise comparisons. The efficacies of treatments between groups were tested by means of Mann-Whitney U Test.

Friedman Test- effect of therapy in trial group

Table 1 Friedman Test- effect of therapy in trial group

	Mean	Std. Deviation	Mean Rank	Asymp. Sig	
BT	21.9500	4.53611	4.00		
DT4	9.0500	3.61976	3.00	000	
DT7	2.0000	1.65434	1.95	.000	
AF	.1500	.48936	1.05		

(BT- Before Treatment, DT4- During Treatment 4th Day, DT7-During Treatment 7th Day, AF- After Follow Up)

There was significant change in the effect of therapy after treatment and after follow up period from the assessment.

Friedman Test- effect of therapy in control group

 Table 2 Friedman Test- effect of therapy in control group

	Mean	Std. Deviation	Mean Rank	Asymp. Sig
BT	21.5500	4.17354	4.00	
DT4	9.5000	3.03488	3.00	.000
DT7	2.8500	1.98083	1.95	
AF	.3500	.58714	1.05	

There was significant change in the effect of therapy after treatment and after follow up period from the assessment.

Effect of therapy between trial and control groups

Mann-Whitney U Test - for comparison of effect of therapy between groups

 Table 3 Effect of therapy between trial and control group

	Mean Rank	Sum of Ranks	Mann-Whitney U	Asymp. Sig. (2- tailed)
Trial	22.08	441.50	168.500	.392
Control	18.92	378.50	108.300	.392

The statistical significance was assessed using Mann Whitney U test with mean rank in trial and control groups of 22.08 and 18.92 respectively and sum of ranks 441.50 and 378.50 respectively.

Percentage of Relief

Symptoms	BT vs AT Trial	BT vs AT Control	BT vs AF Trial	BT vs AF Control
Nausea and vomiting	100	93	100	100
Tremor	96	97	100	100
Paroxysmal sweats	95	90	100	100
Anxiety	77	73	96	94
Agitation	87	85	100	100
Tactile disturbances	95	85	100	100
Auditory disturbances	100	100	100	100
Visual disturbances	100	50	100	100
Head and fullness in head	82	77	100	94
Orientation and				
clouding of	100	100	100	100
sensorium				
Total	91	86	99	98

Table 4 - % of relief

The percentage of relief was more in trial group when compared with the control. After the analysis, it was found that, the effect of therapy with in the groups, both trial and control groups were statistically significant. But on comparison between trial and control group in their efficacies, it is established that there was no statistically significant difference.

DISCUSSION

Discussion on Alcohol Withdrawal syndrome

Alcohol withdrawal symptoms can be classified as acute and protracted categories. The acute alcohol symptoms are nausea, vomiting, tremor, paroxysmal sweats, tactile disturbances, auditory disturbances, visual disturbances, head ache, fullness in head and orientation and clouding of sense orientation¹².

On sudden abstinence from *madya*, *Agnimāndya* definitely occurs. It will lead to formation of *āma* and obstruction to the *srotus* and leading to the manifestations of the above mentioned symptoms. From this aetiopathogenesis of disease and on assessment of the major symptoms, it can be concluded that the initial presentations are of Vātakaphaja in nature. *Ajamoda* due to its *kațu rasa* and katu *vipāka*, *uṣṇa vîrya* and *dîpana* properties pacifies, *Kapha* and also in fact āma. *Ajamoda arka* is *KaphaVātahara* so, anulaomana of *Vātā is* also attained by *the drug*. So, Ajamoda arka seems as an ideal choice in the initial stage of Madātyaya.

Discussion of the effect of therapy

It was observed that trial and control group showed significant effect on nausea and vomiting, tremor and paroxysmal sweats after the intervention. The tremor is be considered as the symptom occurring due to aggravated $V\bar{a}ta$ in the body which is reduced due to *the Vātahara* property and *srotošodhana* action of the drug. In case of anxiety, both trial and control groups showed significant effect after treatment. The reduction in symptom of the trial drug could be considered due to its tranquilizing effect.¹⁵ In case of agitation both trial and control group also showed significant effect after therapy. The reduction in agitation could be considered due to the tranquilizing effect and also the *Vātaanulomana* property.

In case of tactile disturbances both trial and control group showed significant effect. The characteristic feature of *sparsa*

is due to $V\bar{a}ta^{16}$ and the reduction in tactile disturbances could be thus considered due to the $V\bar{a}takaphahara$ property. It was observed that, symptoms such as auditory disturbances, visual disturbances and orientation and clouding of sensorium, showed an insignificant effect in both the groups.

Effect of Therapy in Between Groups

There was no significant difference in between the trial and control group in overall efficacy. Both the groups were having a reduction in mean score which indicates that both groups were effective but of no significant difference in between them. Considering the percentage of relief, it was found that trial group had better efficacy than the control in AWS.

Discussion of the Drug and Mode of Action of the drug

Five *kalpanās* or mode of kashayas have been mentioned in Arkaprakāśa¹⁴, among that *arka* is considered as superior because of its increased potency and immediate action when compared with the others. The mode of action of *Ajamoda arka* is mentioned as *Vāta Kaphahara* and *dīpana*, and hence effective in *ajirṇa* and *agnimāndya*, and especially in *kostharogās* of predominantly *Vāta Kapha in nature. Ajamoda is* having the property of *hrdya* and also *balya*.¹⁷ As it is having a property of *hrdya* it is beneficial to *hrdaya*, which is the *stāna* of *rasa, ojas* and *manas* and beneficial for diseases of such a nature. From various research works it have been observed that when tested in rats, that essential oil of *Ajamoda* is having tranquillizing, anticonvulsant activities and CNS activity, which is quite noteworthy here¹⁵ and is potent to treat an alcoholic, especially in case of AWS.

The methanolic and aqueous extract of *Apium graveolens* exhibits highly significant inhibition of gastric lesions¹⁸. *Apium graveolens* also have anti- inflammatory activity so it is advisable in alcohol related joint pains. *Aştangalavana* is explained in *Kapahaja madātyaya*. It is specially indicated for *Agni sandhīpana* and *srotovisodhana*¹¹. Most of the drug of *Aştangalavana* is dīpana, pācana and *Vatānulomana*. So, in the initial phase of AWS it is capable of removing *āma* and *srotorodha* and infact the disease.

Administration of *Ajamoda arka* which is *kaţu rasa* and *vipāka, uṣna virya* helps to get rid of *removing the obstruction in the corresponding srotuses*. Because of its *dīpana* property it kindles *agni to its normalcy and also normalises the activities of manas* In comparison with *Aṣtāngalavanayukta takṛa, Ajamoda arka* found to be of better action because of potency and rapid action of the arka form of the drug.

CONCLUSION

The study concluded that 20 ml of *Ajamoda arka* for 7 days has got significant effect in reducing signs and symptoms of alcohol withdrawal and effect retained till follow up. But when compared with 6 gm. of *Astāngalavanayukta takra* for 7 days *there* was no significant difference in efficacy. Such drugs are making a physician from the Ayurvedic branch of medicine confident in managing conditions such as AWS. Further studies are having scope and are the need of the hour so as to help the affected mankind.

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How to cite this article:

Jiljith A, Jithesh M and Satheesh K., 2019, Effect of ajamoda arka in Alcohol Withdrawal Syndrome- a Randomized Controlled Trial. *Int J Recent Sci Res.* 10(05), pp. 32178-32181. DOI: http://dx.doi.org/10.24327/ijrsr.2019.1005.3413
