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A Comparative Clinical Study on the Effect of *Mrudvikasava* and *Ashwagandhadyarista* in *Madatyaya* with special reference to Alcohol Withdrawal Syndrome

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Abstract

Introduction: Alcohol Withdrawal Syndrome (AWS) is a composite and potentially life-threatening ailment that arises in individuals who have been consuming alcohol in excess and abruptly decrease or cease their alcohol intake. It comes under the heading *Madatyaya* in ayurveda due to same cause and general signs & symptoms. **Aim and objectives**: The aim of the study is *to compare the clinical efficacy of Mrudvikasava and Ashwagandhadyarishta in Madatyaya W.S.R. to Alcohol Withdrawal Syndrome.* **Materials and Methods:** After attaining endorsement of Institutional ethics committee & informed consent, 40 patients with *Madatyaya* were aimlessly allocated to two groups (20 in each group) for a clinical trial. In group A, *Mrudvikasava* was given and the drug *Ashwagandhadyarishta* was given in Group B for 30 days along with 15 days of follow up. **Result:** The clinical data shows that both the drugs presented the significant effects by reductions in CIWA-Ar Scale and Alcohol Craving Screening Questionnaire after completion of therapy. **Conclusion:** It can be concluded that clinically *Mrudvikasava* and *Ashwagandhadyarishta* are effective and free from any adverse outcome for the management of *Madatyaya*.

Keywords – Alcohol Withdrawal Syndrome, *Madatyaya*, *Mrudvikasava, Ashwagandhadyarishta, Ayurveda*

Introduction

Alcohol consumption is a global phenomenon, and its excessive and prolonged use can have detrimental effects on physical and mental health. Alcohol dependence is characterized by physiological and psychological reliance on alcohol, which, when interrupted, can lead to a cascade of symptoms known as Alcohol Withdrawal Syndrome (AWS). In ayurveda, alcohol is explained as *Madya* or *Sura.* Likewise, acute alcoholism can be understood as *Mada* and lastly

Madatyaya includes a wide range of alcohol related problems like – alcohol addiction or alcohol use disorder (AUD), alcohol withdrawal syndrome (AWS) or chronic alcoholism.

According to ayurveda science, *Madatyaya* is a *Tri-doshaja* disease[1] having *Vata-Pitta* predominantly in chronic manifestations. Here, the *Tamo Guna Pradhan Madya* also produces a disturbance in intellectual properties.[2] It is four types – *Vataj*, *Pittaj*, *Kaphaj* & *Sannipataj Madatyaya*.[3] The *Asav-Arishta* is a form of *Madya* which is used as *Aushadh* in management of *Madatyaya*.[4] This is an example of *Hetu-vyadhivipareetarthakari Chikitsa.*

The trial drugs, *Mrudvikasava* and *Ashwagandhadyarishta* have various type of ingredients which work on *Agni* and all *Dosha* combinedly. In *Madatyaya, Mansika Dosha (Raja & Tama)* also vitiated but these drugs also have some contents like – *Ahswagandha*, *Vacha* etc. which are *Medhya* (brain tonics) and work on brain. In chronic intake of alcohol, patients get emaciated due to *Vata Dosha* for which it also requires *Balya Aushadh*. Both the drugs also have some ingredients, which are *Balya* and *Vatanulomaka*.

Material and methods

Ethical consideration:

Study was approved by Institutional ethics committee (IEC/ACA/2021/02-21) and was registered prospectively in the clinical trial registry of India vide registration number CTRI/2022/04/042228.

Selection of patients:

The trial was incorporated on 40 clinically diagnosed patients of *Madatyaya* (AWS) fulfilling the inclusion criteria were selected from National Institute of Ayurveda Hospital, Jaipur.

Criteria for selection of patients:

Inclusion criteria:

- Patients having history of alcohol consumption along with clinical manifestation (mild & moderate) of alcohol withdrawal syndrome.
- Age between 20-60 years.
- Patients were selected randomly, irrespective of gender, economical, educational and marital status.
- Patients who gave consent.

Exclusion criteria:

- Patients suffering from any kind of major systemic illness such as Malignancy, HTN, Diabetes, Cardiac disease, HIV, Tuberculosis (mainly pulmonary) etc.
- Alcohol addicted patients suffering from liver failure, gastrointestinal bleeding,

hyperacidity, belching, cerebellar degeneration etc.

- Patients with severe clinical manifestations of alcohol withdrawal syndrome.
- Pregnant women and lactating mothers.
- Patients who were not considering the proper instructions given to them, highly violent patients, suffering from major psychiatric illness.

Withdrawal criteria:

- Unwillingness to continue with the study.
- Patients with irregular follow- up.
- Intolerance to medicine.
- Development of any other worst condition requiring some specific treatment.

Assessment criteria:

A. Clinical Institute Withdrawal Assessment Alcohol Scale Revised (CIWA-AR)
B. Alcohol Craving Questionnaire-Short Form Revised (ACQ-SF-R)
C. Pathological Assessment -

✓ Hemogram - CBC

✓ Liver function test - Serum Bilirubin (D), Serum Bilirubin (I), SGOT, SGPT, Total Protein, Alkaline Phosphatase

Sample size: Sample size of 20 (in each group) was selected for the study.

Randomization:

Randomization was done using computer generated randomization method. Randomization plan was generated on www.randomization.com in which 44 patients were randomized into 11 blocks. Randomization plan can be replicated using seed number 26479.

Blinding and Allocation concealment:

It was an open label study and no blinding was done. Allocation concealment was done with the help of sequentially numbered, opaque, sealed envelopes. Randomization sequence generated was sealed in opaque envelopes by an independent person not involved in the study. The envelopes were then sequentially numbered and cases were enrolled following the number.

Consent of patients: All the patients selected for the trial have explained the nature of the study, and their consent was obtained on the pro forma before enrolment in the study.

Grouping: Registered patients were divided randomly in two groups –

- ✓ **Group A:** 20 clinically diagnosed patients of *Madatyaya* (AWS) were treated with *Mrudvikasava.*
- ✓ **Group B:** 20 clinically diagnosed patients of *Madatyaya* (AWS) were treated with *Ashwagandhadyarishta.*

Table 1 Ingredients of *Mrudvikasava*[5]:

S. No.	Drug name	Botanical name	Part used	Quantity
1.	*Mrudvika*	*Vitis vinifera* Linn.	Fruit	5 kg
2.	*Badara*	*Zizyphus jujube*	Root bark	2 kg
3.	*Madhooka*	*Madhuca indica* J.F. Gmel.	Flower	1 kg
4.	*Shunthi*	*Zingiber officinale* Rosc.	Rhizome	½ kg
5.	*Maricha*	*Piper nigrum* Linn.	Fruit	½ kg
6.	*Pippali*	*Piper longum* Linn.	Fruit	½ kg
7.	*Dalcheeni*	*Cinnamomnm zeylanicum* Breyn.	Bark	½ kg
8.	*Ela*	*Elettaria cardamomum* Maton.	Seed	½ kg
9.	*Tejapatra*	*Cinnamomnm zeylanicum*	Leaves	½ kg
10.	*Jayphala*	*Myristica fragrans* Houtt.	Seed	½ kg
11.	*Javitri*	*Myristica fragrans* Houtt.	Mace (Kosha)	½ kg
12.	*Lavanga*	*Syzygium aromaticum* Linn.	Flower bud	½ kg
13.	*Akarakara*	*Anacyclus pyrethrum* DC	Root	½ kg
14.	*Kushtha*	*Saussurea lappa* C.B. Clarke	Root	½ kg
15.	*Poogphala*	*Areca catechu* Linn.	Fruit	½ kg
16.	*Nagakeshara*	*Mesua ferrea* Linn.	Stamen	½ kg
17.	*Shakkara*	Sugar		20 kg
18.	*Jala*	Water		65 L

Table 2 Ingredients of *Ashwagandharishta*[6]:

S. No.	*Drug name*	*Botanical name*	*Part Used*	*Quantity*
1.	*Ashwagandha*	*Withania somnifera Linn*	*Root*	*2.4 kg*
2.	*Musali*	*Chlorophytum tuberosum*	*Root*	*960 g*

3.	*Manjishtha*	*Rubia cardifolia*	*Root*	*480 g*
4.	*Haritaki*	*Terminalia chebula Retz.*	*Pericarp*	*480 g*
5.	*Haridra*	*Curcuma longa Linn*	*Rhizome*	*480 g*
6.	*Daruharidra*	*Berberis aristata DC*	*Stem*	*480 g*
7.	*Yashtimadhu*	*Glycyrrhiza glabra Linn*	*Root*	*480 g*
8.	*Rasna*	*Pluchea lanceolata CB Clarke*	*Root/Leaf*	*480 g*
9.	*Vidari*	*Pueraria tuberosa DC*	*Root/Tuber*	*480 g*
10.	*Partha (Arjuna)*	*Terminalia arjuna Roxb.*	*Stem/Bark*	*480 g*
11.	*Mustaka (Musta)*	*Cyperus rotundus Linn.*	*Rhizome*	*480 g*
12.	*Trivrita*	*Ipomoea turpenthum Linn*	*Root*	*480 g*
13.	*Ananta (Shveta Sariva)*	*Hemidesmus indicus R. Br*	*Root*	*384 g*
14.	*Shyama (Krishna Sariva)*	*Cryptolepis buchanani Roem Schult.*	*Root*	*384 g*
15.	*Shveta Chandana*	*Santalum album Linn*	*Heartwood*	*384 g*
16.	*Rakta Chandana*	*Pterocarpus santalinus Linn*	*Heartwood*	*384 g*
17.	*Vacha*	*Acorus calamus Linn.*	*Rhizome*	*384 g*
18.	*Chitraka*	*Plumbago zeylanica Linn.*	*Root*	*384 g*
19.	*Jala* *for decoction* *Reduced to*	*Water*		*98.304 L* *12.288 L*
20.	*Makshika (Madhu)*	*Honey*		*14.400 kg*
21.	*Dhataki*	*Woodfordia fruticosa Kurz.*	*Flower*	*768 g*
22.	*Shunthi*	*Zingiber officinale Rosc.*	*Rhizome*	*96 g*
23.	*Maricha*	*Piper nigrum Linn.*	*Fruit*	*96 g*
24.	*Pippali*	*Piper longum Linn.*	*Fruit*	*96 g*
25.	*Tvaka*	*Cinnamomnm zeylanicum Bregn*	*Stem/Bark*	*192 g*

26.	*Ela (Sukshmaila)*	*Elettaria cardamomum Maton*	*Seed*	*192 g*
27.	*Patra (Tejpatra)*	*Cinnamomum tamala Nees & Ebern*	*Leaf*	*192 g*
28.	*Priyangu*	*Callicarpa macrophylla Vahal*	*Flower*	*192 g*
29.	*Nagakeshara*	*Mesua ferrea Linn.*	*Stamen*	*96 g*

Table 3 Administration of trial drug:

Name of group	**Name of drug**	**Dose & time of administration**	**Route of administration**	**Duration**	***Anupana***
Group A	*Mrudvikasava*	30 ml, twice a day	Oral	30 days	Equal quantity of water
Group B	*Ashwagandhadyarista*	30 ml, twice a day	Oral	30 days	Equal quantity of water

Outcome measures:

- ✓ **Primary outcome –** changes in CIWA-Ar scale & Alcohol craving questionnaire scale
- ✓ **Secondary outcome –** changes in CBC & LFT parameters

Routine examination and assessment:

The full details of history & physical examination of patient were recorded as per the proforma. Clinical & physiological assessment was done before treatment, during treatment & at the end of the treatment and results were analyzed with appropriate statistical tests.

Statistical Analysis:

Statistical analysis was performed using statistical software GraphPad In stat trial version 3.10. For intragroup comparison of non-parametric data, Wilcoxon matched-pairs signed rank test was employed whereas intergroup comparison for non-parametric data was done using Mann Whitney U test. Paired t-test was used for intragroup comparison of parametric data, whereas Unpaired t-test was used for intergroup comparison.

Observations and Results

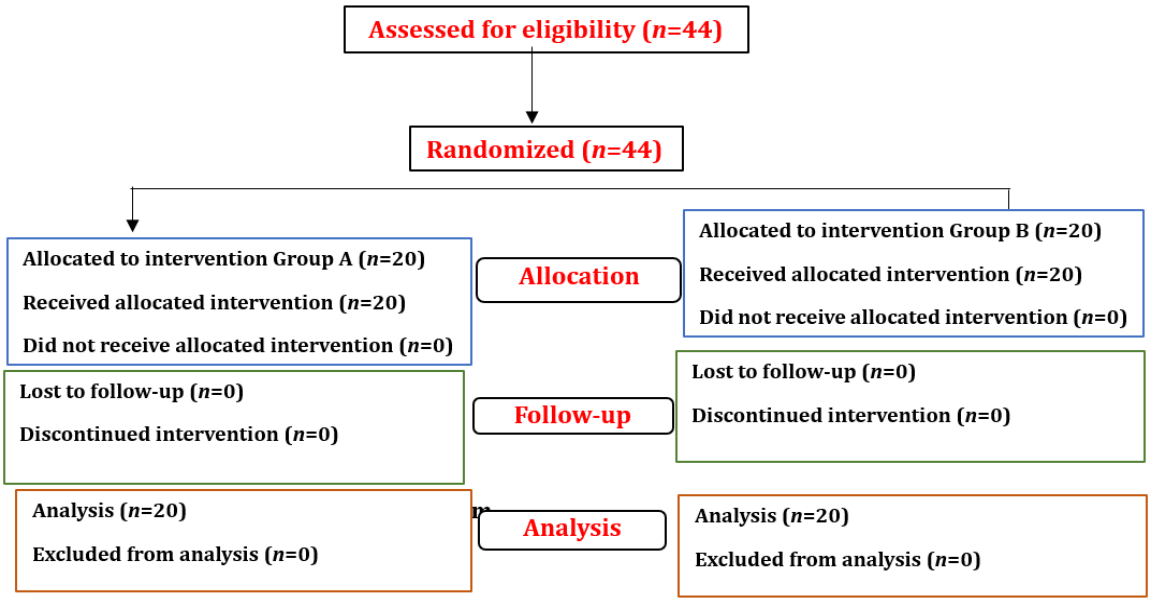

Table 4 Intra group comparison of CIWA-Ar scale

SYMPTOMS	Group	N	Mean		Diff.	% Of Relief	SD±	SE±	P value	Result
			BT	AT						
Nausea/vomiting	A	20	2.15	0.50	1.65	76.74	1.46	0.33	**<0.0001**	**ES**
	B	20	1.40	0.35	1.05	75.00	1.05	0.23	**0.0002**	**ES**
Tremors	A	20	1.35	0.70	0.65	48.15	0.75	0.17	**0.0020**	**VS**
	B	20	1.80	1.20	0.60	33.33	0.60	0.13	**0.0010**	**ES**
Anxiety	A	20	2.40	1.95	0.45	18.75	0.60	0.1	**0.0078**	**VS**
	B	20	2.60	1.55	1.05	40.38	0.69	0.15	**<0.0001**	**ES**
Agitation	A	20	1.20	0.60	0.60	50.00	0.75	0.17	**0.0039**	**VS**
	B	20	1.35	0.65	0.70	51.85	0.73	0.16	**0.0010**	**ES**
Paroxysmal sweat	A	20	0.55	0.10	0.45	81.82	0.69	0.15	**0.0156**	**S**
	B	20	0.55	0.30	0.25	45.45	0.44	0.10	**0.0625**	**NS**
Orientation& clouding of sensorial	A	20	0.25	0.15	0.10	40.00	0.31	0.07	**0.5000**	**NS**
	B	20	0.35	0.15	0.20	57.14	0.37	0.08	**0.1250**	**NS**
Tactile disturbances	A	20	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**-**
	B	20	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**-**
	A	20	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**-**

Auditory disturbances	B	20	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	-
Visual disturbances	A	20	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	-
	B	20	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	-
Headache	A	20	0.40	0.10	0.30	75.00	0.57	0.13	**0.0625**	**NS**
	B	20	0.65	0.25	0.40	61.54	0.50	0.11	**0.0078**	**VS**

(N: Number of patients; BT: Before Treatment; AT: After Treatment; %: Percentage; S.D: Standard Deviation; SE: Standard Error; ES: Extremely Significant; VS: Very Significant; NS: Not Significant; S: Significant)

Table 5 Intra group comparison of Alcohol Craving Screening Questionnaire

SYMPTOMS	Group	N	Mean		Diff.	% Of Relief	SD±	SE±	P value	Result
			BT	AT						
If I had some alcohol, Iwould probably drink it?	A	20	3.65	1.15	2.50	68.49	1.24	0.28	**<0.0001**	**ES**
	B	20	4.50	1.90	2.60	57.78	1.39	0.31	**<0.0001**	**ES**
I miss drinking?	A	20	5.25	1.10	4.15	79.05	1.73	0.39	**<0.0001**	**ES**
	B	20	5.40	1.50	3.90	72.22	1.68	0.38	**<0.0001**	**ES**
I am not making any plans to drink?	A	20	4.30	1.35	2.95	68.60	1.76	0.39	**<0.0001**	**ES**
	B	20	3.40	1.35	2.05	60.29	1.79	0.40	**0.0001**	**ES**
I could not stop myself from drinking if I had some alcohol here?	A	20	4.50	1.40	3.10	68.89	1.80	0.40	**<0.0001**	**ES**
	B	20	3.80	1.40	2.40	63.16	1.57	0.35	**<0.0001**	**ES**
I want to drink so bad I can almost taste it?	A	20	3.80	1.05	2.75	72.37	2.24	0.50	**<0.0001**	**ES**
	B	20	4.05	1.15	2.90	71.60	1.65	0.37	**<0.0001**	**ES**
I would feel less irritable if used alcohol now?	A	20	5.20	1.65	3.55	68.27	1.79	0.40	**<0.0001**	**ES**
	B	20	5.20	1.65	3.55	68.27	1.67	0.37	**<0.0001**	**ES**
If I used alcohol, I would feel less tensed?	A	20	4.90	1.30	3.60	73.47	1.76	0.39	**<0.0001**	**ES**
	B	20	4.50	1.55	2.95	65.56	1.67	0.37	**<0.0001**	**ES**
Drinking would not be very satisfying?	A	20	4.05	1.60	2.45	60.49	1.54	0.34	**<0.0001**	**ES**
	B	20	4.05	1.55	2.50	61.73	1.64	0.37	**<0.0001**	**ES**

I would feel less restless if I drink?	A	20	4.90	1.35	3.55	72.45	1.82	0.41	**<0.0001**	**ES**
	B	20	4.70	1.85	2.85	60.64	1.31	0.29	**<0.0001**	**ES**
If I was using alcohol, I would feel less nervous?	A	20	4.90	1.30	3.60	73.47	1.76	0.39	**<0.0001**	**ES**
	B	20	4.50	1.55	2.95	65.56	1.67	0.37	**<0.0001**	**ES**
It would be easy to pass the chance to use alcohol?	A	20	3.15	1.15	2.00	63.49	1.69	0.38	**<0.0001**	**ES**
	B	20	2.75	1.25	1.50	54.55	1.88	0.42	**0.0020**	**VS**
Drinking would put me in a better mood?	A	20	4.25	1.10	3.15	74.12	2.11	0.47	**<0.0001**	**ES**
	B	20	4.95	1.45	3.50	70.71	1.88	0.42	**<0.0001**	**ES**

(N: Number of patients; BT: Before Treatment; AT: After Treatment; %: Percentage; S.D: Standard Deviation; SE: Standard Error; ES: Extremely Significant; VS: Very Significant)

Table 6 Intra group comparison of pathological assessments

SYMPTOMS	Group	N	Mean		Diff.	% Of Relief	SD±	SE±	T value	P value	Result
			BT	AT							
Haemoglobin	A	20	13.34	13.68	-0.34	-2.54	0.98	0.22	1.545	**0.1388**	**NS**
	B	20	13.84	14.20	-0.36	-2.58	0.85	0.19	1.872	**0.0766**	**NS**
Total leucocyte count	A	20	6.89	6.73	0.16	2.38	1.83	0.41	0.4018	**0.6923**	**NS**
	B	20	7.04	7.01	0.03	0.48	2.56	0.57	0.0594	**0.9532**	**NS**
Neutrophils	A	20	56.11	56.21	-0.11	-0.20	8.96	2.00	0.0546	**0.9570**	**NS**
	B	20	55.46	56.41	-0.95	-1.71	7.89	1.76	0.5380	**0.5968**	**NS**
Leucocytes	A	20	33.05	32.00	1.05	3.19	7.33	1.64	0.6434	**0.5277**	**NS**
	B	20	31.20	31.70	-0.50	-1.61	6.18	1.38	0.3639	**0.7199**	**NS**
Eosinophils	A	20	3.34	2.12	1.22	36.55	1.82	0.41	2.996	**0.0074**	**VS**
	B	20	3.52	4.07	-0.55	-15.70	3.18	0.71	0.7765	**0.4470**	**NS**
Monocytes	A	20	8.04	7.31	0.73	9.10	1.71	0.38	1.919	**0.0702**	**NS**
	B	20	8.00	7.58	0.42	5.24	2.40	0.54	0.7794	**0.4454**	**NS**
Basophils	A	20	1.47	1.23	0.24	16.21	2.07	0.46	0.5144	**0.6129**	**NS**
	B	20	0.92	0.77	0.15	16.52	0.39	0.09	1.731	**0.0997**	**NS**
	A	20	0.51	0.40	0.11	20.80	0.16	0.04	2.934	**0.0085**	**VS**

Bilirubin (Direct)	B	20	0.43	0.57	-0.14	-32.49	0.24	0.05	2.627	**0.0166**	**S**
Bilirubin (Indirect)	A	20	0.76	0.67	0.09	11.86	0.36	0.08	1.128	**0.2733**	**NS**
	B	20	0.89	0.74	0.15	17.10	0.40	0.09	1.691	**0.1072**	**NS**
SGOT	A	20	99.03	38.16	60.87	61.47	19.35	4.33	14.066	**<0.0001**	**ES**
	B	20	90.81	51.95	38.85	42.79	11.63	2.60	14.936	**<0.0001**	**ES**
SGPT	A	20	80.93	36.04	44.89	55.47	14.44	3.23	13.905	**<0.0001**	**ES**
	B	20	108.51	51.57	56.94	52.48	19.13	4.28	13.311	**<0.0001**	**ES**
Total protein	A	20	7.76	7.53	0.23	2.90	1.15	0.26	0.8755	**0.3922**	**NS**
	B	20	7.56	7.69	-0.13	-1.72	1.02	0.23	0.5709	**0.5747**	**NS**
ALP	A	20	108.85	93.75	15.10	13.87	18.83	4.21	3.585	**0.0020**	**ES**
	B	20	94.80	99.05	-4.25	-4.48	22.81	5.10	0.8331	**0.4151**	**NS**

(N: Number of patients; BT: Before Treatment; AT: After Treatment; %: Percentage; S.D: Standard Deviation; SE: Standard Error; ES: Extremely Significant; VS: Very Significant; NS: Not Significant; S: Significant)

Table 7 Inter group comparison of CIWA-Ar scale

Variable	Mean Diff		SD ±		SE ±		U' value	P value	Result
	Group A	Group B	Group A	Group B	Group A	Group B			
Nausea/ vomiting	1.650	1.050	1.461	1.050	0.3267	0.2348	245.50	**0.2070**	**NS**
Tremors	0.6500	0.6000	0.7452	0.5982	0.1666	0.1338	201.50	**0.9761**	**NS**
Anxiety	0.4500	1.050	0.6048	0.6863	0.1352	0.1535	292.0	**0.0070**	**VS**
Agitation	0.6000	0.7000	0.7539	0.7327	0.1686	0.1638	217.0	**0.6241**	**NS**
Paroxysmal sweat	0.4500	0.2500	0.6863	0.4443	0.1535	0.09934	225.00	**0.4081**	**NS**
Orientation& clouding of sensorial	0.1000	0.1500	0.3078	0.3663	0.06882	0.08192	210.00	**0.6538**	**NS**
Tactile disturbances	0.00	0.000	0.000	0.000	0.000	0.0000	000.00	**0.000**	**-**
Auditory disturbances	0.00	0.000	0.000	0.000	0.000	0.0000	000.00	**0.000**	**-**

Visual disturbances	0.00	0.000	0.000	0.000	0.000	0.0000	000.00	**0.000**	**-**
Headache	0.3000	0.4000	0.5712	0.5026	0.1277	0.1124	226.00	**0.3980**	**NS**

(N: Number of patients; BT: Before Treatment; AT: After Treatment; %: Percentage; S.D: Standard Deviation; SE: Standard Error; VS: Very Significant; NS: Not Significant)

Table 8 Inter group comparison of Alcohol Craving Questionnaire

Variable	Mean Diff		SD±		SE±		U' value	P value	Result
	Group A	Group B	Group A	Group B	Group A	Group B			
If I had some alcohol, Iwould probably drink it?	2.500	2.600	1.235	1.392	0.2763	0.3112	214.50	**0.6918**	**NS**
I miss drinking?	4.150	3.900	1.725	1.683	0.3858	0.3763	217.00	**0.6483**	**NS**
I am not making any plans to drink?	2.950	2.050	1.761	1.791	0.3939	0.4005	257.00	**0.1151**	**NS**
I could not stop myself from drinkingif I had some alcohol here?	3.100	2.400	1.804	1.569	0.4033	0.3509	249.50	**0.1767**	**NS**
I want to drink so bad Ican almost taste it?	2.750	2.900	2.245	1.651	0.5020	0.3692	206.50	**0.8690**	**NS**
I would feel less irritable if used alcohol now?	3.550	3.550	1.791	1.669	0.4005	0.3733	203.00	**0.9443**	**NS**
If I used alcohol, I would feel less tensed?	3.600	2.950	1.759	1.669	0.3934	0.3733	248.50	**0.1822**	**NS**
Drinking would not bevery satisfying?	2.450	2.500	1.538	1.638	0.3439	0.3663	206.00	**0.8776**	**NS**
I would feel less restless if I drink?	3.550	2.850	1.820	1.309	0.4070	0.2927	253.50	**0.1367**	**NS**
If I was using alcohol, I would feel less nervous?	3.600	2.950	1.759	1.669	0.3934	0.3733	248.50	**0.1822**	**NS**
It would be easy to pass the	2.000	1.500	1.686	1.878	0.3770	0.4199	246.00	**0.2026**	**NS**

chance touse alcohol?									
Drinking would put mein a better mood?	3.150	3.500	2.110	1.878	0.4717	0.4199	217.50	**0.6404**	**NS**

(N: Number of patients; BT: Before Treatment; AT: After Treatment; %: Percentage; S.D: Standard Deviation; SE: Standard Error; NS: Not Significant)

Table 9 Inter group comparison of pathological assessments

Variable	Mean Diff		SD±		SE±		T value	P	Result
	Group A	Group B	Group A	Group B	Group A	Group B			
Haemoglobin	0.3399	0.3656	0.9812	0.8515	0.2194	0.1904	0.0602	**0.9523**	**NS**
Total leucocyte counts	0.1640	0.0340	1.826	2.557	0.4082	0.5718	0.1850	**0.8542**	**NS**
Neutrophils	0.1095	0.9495	8.963	7.893	2.004	1.765	0.3145	**0.7548**	**NS**
Leucocytes	1.054	0.5030	7.326	6.181	1.638	1.382	0.7264	**0.4720**	**NS**
Eosinophils	1.219	0.5525	1.820	3.182	0.4069	0.7116	2.161	**0.0370**	**S**
Monocytes	0.7320	0.4190	1.706	2.404	0.3815	0.5376	0.4748	**0.6376**	**NS**
Basophils	0.2385	0.1520	2.074	0.3928	0.4637	0.0873	0.1833	**0.8555**	**NS**
Bilirubin (Direct)	0.1060	0.1405	0.1616	0.2392	0.0361	0.0534	3.819	**0.0005**	**ES**
Bilirubin (Indirect)	0.0905	0.1530	0.3587	0.4046	0.0802	0.0904	0.5169	**0.6082**	**NS**
SGOT	60.873	38.854	19.354	11.634	4.328	2.601	4.361	**<0.0001**	**ES**
SGPT	44.893	56.938	14.438	19.130	3.228	4.278	2.248	**0.0305**	**S**
Total Protein	0.2250	0.1300	1.149	1.018	0.2570	0.2277	1.034	**0.3077**	**NS**
ALP	15.100	4.250	18.834	22.815	4.211	5.102	2.925	**0.0058**	**VS**

(N: Number of patients; BT: Before Treatment; AT: After Treatment; %: Percentage; S.D: Standard Deviation; SE: Standard Error; ES: Extremely Significant; VS: Very Significant; NS: Not Significant; S: Significant)

Table 10 Distribution of patients according to relief (in percentage)

Relief	Alcohol Withdrawal Group A		Alcohol Withdrawal Group B		Total	
	Patient	%	Patient	%	Patient	%
No relief	0	00	0	00	0	00

Mild (1-25%)	0	00	0	00	0	00
Moderate (26-50%)	18	90.00	19	95.00	37	92.50
Marked (51-75%)	2	10.00	1	5.00	3	7.50
Excellent (76-100%)	0	00	0	00	0	00

Discussion

Probable mode of action of *Mrudvikasava:*

- Most of the ingredients in this *Mrudvikasava* are *Madhura – Katu - Tikta Rasa*, *Laghu – Teekshna Guna*, *Ushna Veerya* and *Katu Vipaka Dravya*.
- Most of the drugs have *Kaphahara* properties, which plays vital role in *Amapachana* and *Ushna & Teekshna* drugs may be helpful to flush out the toxins from the body and correct the *Agni* (digestive fire).
- Because of *Sara Guna* of *Mrudvika* and *Teekshna Guna* of another Dravya, this drug may pass the Blood Brain Barrier and regulates the psychological changes which happen in alcohol withdrawal syndrome.
- In *Mrudvikasava, Mrudvika (Vitis vinifera)* is the chief ingredient. The most important active constituents of *V. vinifera* are phenolic compounds.[7]
- Hepatoprotective effects of *Mrudvika (Vitis vinifera)*: Some studies combined *V. vinifera* with other herbal medicines and investigated the effect their combination in different hepatotoxic models. It seems that the antioxidant, free radical scavenging and anti-inflammatory activities of *V. vinifera* and other herbs are responsible for their hepatoprotective effects[8]. In one study, a diet that included 15% *V. vinifera* powder protected several tissues, including the liver, against oxidative stress induced by 20% ethanol in rats[9]. In this study, it was suggested that the intake of functional food is useful in the prevention of chronic degenerative liver diseases.
- Neuroprotective: The dichloromethane fraction (DF) of *P. longum* and *P. nigrum* was examined for the therapeutic effect of neuron injury after apoplexy using a middle cerebral artery occlusion model in rats. The extract was administered orally in the rat model for 14 days. The model exhibits a significant increase in PSD95, phosphorylated CaMK II (p-CaMK II), calmodin (CaM) and N-methyl D-aspartate receptor subtype 2B

(NR2B).[10] As Ayurveda perspective, *Katu* & *Tikta Rasa* of *Mrudvikasava* may help to keep mind alert.

Probable mode of action of *Ashwagandhadyarishta:*

- Most of the ingredients in this *Ashwagandhadyarishta* are *Madhura – Katu - Tikta Rasa*, *Laghu – Teekshna Guna*, *Ushna Veerya* and *Katu Vipaka Dravya*.
- In this formulation – *Haridra*, *Manjishtha*, *Ela*, *Chandan* are *Vishaghna Dravya*[11], which counteract the effects of *Madya*, because *Madya* has similar properties like *Visha*.[12]
- In *Ashwagandhadyarishta, Ashwagandha (Withania somnifera)* is the chief ingredient.
- *Ashwagandha (Withania somnifera)* is very revered herb of the Indian Ayurvedic system of medicine as a *Rasayana* (tonic). It is used for various kinds of disease processes and specially as a nervine tonic.
- Sitoindosides and acylsterylglucosides in *Ashwagandha* are anti-stress agents. Active principles of *Ashwagandha*, for instance the sitoindosides VII–X and Withaferin-A, have been shown to have significant anti-stress activity against acute models of experimental stress[13].
- Cognition promoting effect of *Ashwagandhadyarishta: Ashwagandha* is a well-known Ayurvedic *Rasayana*, and belongs to a sub-group of *Rasayana* known as *Medhyarasayanas*. *Medhya* typically refers to the mind and mental/intellectual capacity. Thus, *Medhya Rasayana* like *Ashwagandha*, is used to promote intellect and memory. The cognition-promoting effect of *Medhya Rasayana* is best seen in children with memory deficits, or when memory is compromised following head injury, or a prolonged illness and in old age[14].
- The available scientific data support that *Ashwagandhadyarishta* is a real potent regenerative tonic, due to its multiple pharmacological actions like anti-stress, neuroprotective, antitumor, anti-arthritic, analgesic and anti-inflammatory etc. It is useful for different types of diseases like Alcohol withdrawal syndrome, Parkinson, dementia, memory loss, stress induced diseases and others.

Conclusions

Based on the results, it was found that both *Mrudvikasava* (Trial drug) and *Ashwagandhadyarishta* (control drug) were effective in lowering sign and symptoms and clinically safe in patients with *Madatyaya*.

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Conflicts of interest

There are no conflicts of interest.

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