



A Clinical Trial To Assess The Effect of Punarnavadi Ghrita On Madatyaya

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ABSTRACT

Madatyaya is a (*Vyadhi*) disease mention by *Ayurvedacharyas* and in contemporary science it is correlated with “Alcoholism”. Now days it is spreading like an evil in the society. The present study deals with assessment of the clinical effect of “*Punarnavadi Ghritta*” in the management of “*Madatyaya*” w.s.r. to withdrawal symptom. In the study particular symptoms of *Madataya* are assessed on the basis of a self prepared gradation index. Blood Examinations Hb gm%, TLC, DLC, ESR, LFT are done to assess the efficacy of the drug. For clinical study a randomized open clinical trial of 30 days on 30 patients in Drug De-addiction was conducted where patients were assessed before treatment, on follow-up on 15th day and after treatment. The patients were treated with *Punarnavadi Ghritta*. The before treatment and after treatment comparison of data reveals that treatment given to 30 patients shows significant ($P < 0.05$) results in most of subjective parameters and objective parameters. The study revealed that the test drug *Punarnavadi Ghritta* is effective in improvement of sign symptoms and laboratory investigations in the patients of withdrawal symptoms of *madatyaya*.

Key words: *Madatyaya, Sign and symptoms, Punarnavadi, Ghritta-*

INTRODUCTION

Madya is well described in all the ancient texts. It is in use from the ancient times. *Madya* is prepared from different types of ingredients and they have different *guna* and *karma*. Hence these drinks have both useful and harmful effects. If taken in an appropriate manner in optimum dose, at an appropriate time, along with wholesome food, in accordance with one’s own strength and with a happy mood, *madya* works as *Amritta*.¹ In *Charaka Samhita Madya* is mentioned as the great wisdom of the *Ashwini kumars*, which is the power of *Saraswati*, which is the *oja* of *Indra*, which is the ‘*Soma*’ prepared in the ‘*Sautramani yagya*’, which is the destroyer of sorrow, unhappiness, fear and distress, which is powerful, and when taken produces happiness which increases love, joy, speech and nourishment and reduces tension, and praised as the joyful wine by the gods and mortals, should be taken in joyfull manner.² But its excessive and improper use results in *Madatyaya*³; which is similar to alcoholism because *madatyaya* has clinical symptoms similar to Alcoholism. The *samanya lakshanas* of *madatyaya* mentioned in *Ayurveda*⁴ can be correlated with the withdrawal symptoms of chronic alcoholism.⁵ As per *Ayurveda Madya* is poison because there are 10 *gunas* (properties) of poisons by which it act on body, which are exactly similar with all *gunas* (properties) of *Madya*.^{6,7} Though *Madya* is poison, but when person drinks it in an adequate dose, by proper manner with proper diet, it acts as an *Amrit*. But if anyone consume *Madya* in over dose and by improper manner then it destroyes the *Ojadhatu* in human body as all the *gunas* of *Ojadhatu* are exactly opposite to the *gunas* of *Madya*.⁸ In *ayurveda Madatyaya* is described as a *Tridoshaja Vyadhi* with predominance of *Kapha Dosha* and imbalance of *Agni*.⁹ But in modern science the alcohol addiction/abuse is a disorder which can be better

treated by stopping the consumption of alcohol and patient who want to leave alcohol consumption, by sudden withdrawal of alcohol, they suffer from serious withdrawal symptoms; which force them to take alcohol again. These withdrawal symptoms act as a big hurdle in treatment of alcohol addicted patients. In *Chikitsa of Madataya Acharya Charak* has mentioned the drugs which have *Deepana, Pachana, Srotoshodhaka* properties can effectively treat the *Madatyaya*.¹⁰ In the present study the trial drug *Punarnavadi Ghritta* is selected with the reference of *Acharya Chakradatta* mentioned for the treatment of *Madatyaya*.¹¹ It is a herbal preparation and is used as *Rasayana*. *Punarnavadi Ghritta* is made up of *Godugdha, Goghritta, Yashtimadhu, Punarnava* which have very good effect on nervousness, palpitation, tremors, headache, anorexia, fatigue, irritability, lack of concentration, etc. which are the symptom of *Madatyaya*. So the present research work has been undertaken keeping in the view the hazards of *madataya* to the society and providing a safe, economical and better treatment for the patients of *madataya*.

MATERIALS AND METHODS

Aim and objectives:-

To assess the clinical efficacy of *Punarnavadi Ghritta* in sign and symptoms of *Madataya*.

Selection and Preparation of drug

The trial drug *Punarnavadi Ghritta* was selected on the basis of reference of *Acharya Chakradatta*¹¹. The drug was prepared according to procedure as mentioned in the classical text¹¹ in the pharmacy of Uttaranchal Ayurvedic College, Dehradun, under the supervision of *Ras Shashtra* and *Dravya guna* Department. *Punarnava kwath* (8 part), *Yashtimadhu kalka* (1 part), *Go-dugdh* (4 part), *Go-ghritta*(4 part). The first three ingredients were mixed together and the *go-ghritta* was to make *sidhh* (medicated) from them on low fire.

Selection of patients

The patients were selected on the basis of signs and symptoms of *Madatyaya* described in the Ayurvedic texts. The Alcohol Use Disorder Identification Test (AUDIT) is used as a screening test of the patients as per the guidelines of WHO.

Patient criteria

Inclusion criteria

- (a) Patient of age group 18 years to 45 years.
- (b) Patients those having signs and symptoms of "*Madataya*" as mentioned in Ayurvedic texts.
- (c) The Alcohol Use Disorder Identification Test (AUDIT) was used for the screening of the alcoholic patients.
- (d) Patients having drinking history of less than 8 years.

Exclusion criteria

- (a) Occasional drinkers.
- (b) Patients in emergency condition.
- (c) Patients having chronic disorders like ascitis, splenomegaly etc.

Discontinuing criteria

- (a) Any other acute illness develops during the trial.
- (b) Uncontrolled cardinal features.
- (c) Patients not willing to continue

Place of Study

After taking written and informed consent of patient total 30 patients were taken from the *Jagrati Foundation, Drug De-addiction and Rehabilitation centre, Dehradun*.

Plan of Study

The 30 selected patients were treated with Punarnavadi Ghritta 10 ml. in morning and evening for 30 days.

Parameters for Evaluation: Assessment was done on following parameters:

- (a) Symptomatic Improvements
- (b) Laboratory investigations

(a) Symptomatic Improvements:

The particular symptoms of *Madataya* were taken which were present in the patients and these were assessed on the basis of a self prepared gradation index.

Gradation Index:

(1) Daha (Burning sensation) :

Features		Score
Absent	-	0
Occasionally present	-	1
Frequently present	-	2
Continuously present	-	3

(2) Atisaara (Loose stools) :

Features		Score
Absent	-	0
4 loose stools per day	-	1
4 to 8 loose stools per day	-	2
> 8 loose stools per day	-	3

(3) Sweda (Sweating) :

Features		Score
Absent	-	0
Sweating over forehead only	-	1
Sweating in axilla & body folds	-	2
Profuse sweating over whole body	-	3

(4) Prajagrana (Insomnia) :

Features		Score
Sleep of more than 8 hours a day	-	0
Sleep of 6 to 8 hours a day	-	1
Sleep of 4 to 6 hours a day	-	2
Sleep of less than 4 hours a day	-	3

(5) Sharirkampa (Tremors) :

Features		Score
Absent	-	0
Occasionally present	-	1
Present but not disrupts activities	-	2
Disrupts activities	-	3

(6) Trishana (Thirst/Dehydration) :

Features		Score
Absent	-	0
Occasionally present	-	1

Thirst relieved after drinking water	-	2
Thirst not relieved even after drinking water-	-	3

(7) Chardi (Vomiting) :

Features		Score
Absent	-	0
2 times in a day	-	1
4 times in a day	-	2
> 4 times in a day	-	3

(8) Aruchi (Tastelessness) :

Features		Score
Absent	-	0
Occasionally present	-	1
Aruchi even towards good food	-	2
Aruchi towards favorite food	-	3

(9) Pralapa (Irrelevant speech) :

Features		Score
Normal speech	-	0
Occasionally irrelevant speech	-	1
Frequently irrelevant speech	-	2
Continuously irrelevant speech	-	3

(10) Bhrama (Hallucinations) :

Features		Score
Absent	-	0
Occasionally present	-	1
Frequently present	-	2
Continuously present	-	3

(b) Laboratory investigations:-

Blood Examinations – The following blood tests were performed before and after the completion of the trial to assess the efficacy of the drug.

- Hb gm%
- TLC (Total Leukocyte Count)
- DLC (Differential Leukocyte Count)
- ESR (Erythrocyte Sedimentation Rate)
- LFT (Liver Function Test)
- SGOT, SGPT, Total Bilirubin, Direct Bilirubin, Indirect Bilirubin

Statistical Observation and Analysis:-

The information and data collected on the basis of above observations and parameters was processed in statistical manner. Student's paired-t test was applied for statistical analysis in the clinical features and objective parameters of *Madatyaya* to compare the value of significance in the same group at two different occasions i.e. before and after treatment comparison of quantitative data.¹²

- $p > 0.05$ – not significant
- $p < 0.05$ – significant
- $p < 0.01$ – significant
- $p < 0.001$ – highly significant.

Assessment of Improvement on the basis of Sign and Symptoms

Marked Relief :- More than or equal to 75% relief in sign and symptoms.

Moderate Relief :- 50 to 74% relief in sign and symptoms.

Mild Relief :- 25% to 49% relief in sign and symptoms.

No relief :- Below 25% relief in sign and symptoms.

RESULTS AND DISCUSSION

Results on subjective parameters

In *Daha*, there was 55.55% relief, which is statistically insignificant. (p>0.05)

In *Atisara*, there was 66.66% relief, which is statistically insignificant. (p>0.05)

In *Sweda*, there was 50% relief, which is statistically significant. (p<0.05)

In *Prajagarana*, there was 46.15% relief, which is statistically significant. (p<0.05)

In *Sharirkampa*, there was 50% relief, which is statistically significant. (p<0.05)

In *Trishna*, there was 60% relief, which is statistically significant. (p<0.05)

In *Chardi*, there was 50% relief, which is statistically insignificant. (p>0.05)

In *Aruchi*, there was 40% relief, which is statistically significant. (p<0.05)

In *Pralapa*, there was 44.44% relief, which is statistically insignificant. (p>0.05)

In *Bharam*, there was 44.44% relief, which is statistically insignificant. (p>0.05)

Table 1:- Effect of therapy on Subjective parameters

Sign and Symptoms	Mean		Mean diff.	% Relief	S.D. + ₋	S.E. + ₋	't' value	P value	Remarks
	B.T.	A.T.							
<i>Daha</i>	0.9	0.4	0.5	55.55	.7071	.2236	2.236	.052	>0.05
<i>Atisara</i>	0.9	0.3	0.6	66.66	.8432	.2666	2.250	.051	>0.05
<i>Sweda</i>	1	0.5	0.5	50	.5270	.1666	3.000	.015	<0.05
<i>Prajagrana</i>	1.3	0.7	0.6	46.15	.6992	.2211	2.714	.024	<0.05
<i>Sharirkampa</i>	1.2	0.6	0.6	50	.6992	.2211	2.714	.024	<0.05
<i>Trishna</i>	1	0.4	0.6	60	.6992	.2211	2.714	.024	<0.05
<i>Chardi</i>	0.4	0.2	0.2	50	.4216	.1333	1.500	.168	>0.05
<i>Aruchi</i>	1.5	0.9	0.6	40	.6992	.2211	2.714	.024	<0.05
<i>Pralapa</i>	0.9	0.5	0.4	44.44	.5164	.1633	2.449	.057	>0.05
<i>Bhrama</i>	0.9	0.5	0.4	44.44	.5164	.1633	2.449	.057	>0.05

B.T.- Before treatment, A.T. – After Treatment, S.D.- Standard deviation, S.E.- Standard error

Results on Lab Investigation:

In Hb%, there was 17.24% improvement which is statistically highly significant. (p<0.001)

In TLC, there was 10.14% improvement which is statistically significant. (p<0.05)

In DLC, there was 25.24% improvement in polymorphs, 21.24% in lymphocytes, 36.95% in monocytes, 37.50% in eosinophils and 42.85% in basophils, which is statistically insignificant. (p>0.05)

In ESR, there was 27.95% improvement which is statistically significant. (p<0.05)

In SGPT, there was 27.15% improvement which is statistically highly significant. (p<0.001)

In SGOT, there was 50.13% improvement which is statistically significant. (p<0.05)

In Total Bilirubin, there was 40.77% improvement which is statistically highly significant. (p<0.001)

In Direct Bilirubin, there was 46.38% improvement which is statistically significant. (p<0.05)

In Indirect Bilirubin, there was 34.18% improvement which is statistically significant. (p<0.05)

Table 2:- Effect of therapy on Lab. Investigations

Lab. Tests	Mean		Mean diff.	% Relief	S.D. +_	S.E. +_	't' value	P value	Remark	
	B.T.	A.T.								
Hb gm%	11.48	13.46	1.96	17.24	.5452	.1724	-11.4	.000	<0.001	
TLC	9460	8500	960	10.14	531.6	168.1	5.71	.030	<0.05	
DLC	P	61	45.6	15.4	25.24	8.579	2.712	5.67	.083	>0.05
	L	41.9	33	8.9	21.24	8.359	2.643	3.36	.079	>0.05
	M	4.6	2.9	1.7	36.95	1.828	.5783	2.94	.066	>0.05
	E	4.8	3	1.8	37.50	1.686	.5333	3.37	.068	>0.05
	B	0.7	0.4	0.3	42.85	.4830	.1527	1.96	.081	>0.05
ESR	9.3	6.7	2.6	27.95	.6992	.2211	11.7	.011	<0.05	
SGPT	47.44	34.56	12.88	27.15	3.243	1.025	12.5	.000	<0.001	
SGOT	65.60	32.71	32.89	50.13	10.27	3.248	10.1	.018	<0.05	
Total Bilirubin	1.496	0.886	0.610	40.77	.0575	.0182	33.5	.000	<0.001	
Direct Bilirubin	0.623	0.334	0.289	46.38	.0854	.0270	10.6	.021	<0.05	
Indirect Bilirubin	0.863	0.568	0.295	34.18	.1074	.0339	8.68	.016	<0.05	

B.T.- Before treatment, A.T. – After Treatment, S.D.- Standard deviation, S.E.- Standard error, Hb- Haemoglobin, TLC- Total Leukocyte Count, DLC- Differential Leukocyte Count, P- Polymorphs, L- Lymphocytes, M- Monocytes, E- Eosinophils, B- Basophils, ESR- Erythrocyte Sedimentation Rate, SGPT- Serum Glutamic Pyruvic Transaminase, SGOT- Serum Glutamic Oxaloacetic Transaminase

Overall effect of Therapy

Table 3:- Overall effect of therapy on 30 patients

Results	Number	Percentage
Marked Relief	03	10
Moderate Relief	18	60
Mild Relief	0	0
No Relief	09	30
Total	30	100

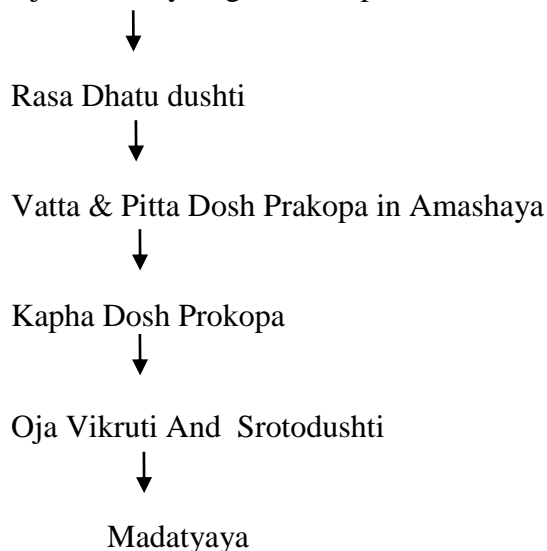
In the study there was marked improvement in 3 (10%) patients and moderate improvement in 18 (60%) patients, no patient noticed with mild relief and there was no relief in 9 (30%) patients.

DISCUSSION

Madatyaya is well explained in all *samhitas*. Different *acharyas* has their different opinions about the types and effects of *madatyaya*. But in ancient literature only *Acharya Kasyapa* has mentioned separately about the *samana samprapti* of *Madatyaya*.¹³

Flow Chart Showing Samanya Samprapti of Madatyaya:

Excessive intake of madya in Ajeerna & by Laghu Satva person



Madatyaya is described as a *tridoshja vyadhi* in *ayurveda* and there are number of drugs, medicines and non-medicinal therapeutic measures for the treatment and prevention of *Madatyaya* mentioned in *ayurvedic* texts. Among all of them “*Punarnavadi Ghritta*” was selected for the clinical trial keeping the views of its general availability and palatability. The trial drug in the form of *ghritta* was given to patients in the dosage of 10 ml. twice a day for one month.

Discussion on Probable Mode of Action of the trial Drug:

The action any drug depends on its properties like *Rasa*, *Guna*, *Veerya*, *Vipaka* and *Prabhava*. The imbalance in *doshas* and *dushyas* of the body is the main causative factor for prevalence of any disease and to cure the disease it is necessary to balance these factors. *Madatyaya* is considered as a *Tridoshja vyadhi* in *ayurvedic* text. It includes the involvement of *dushyas* i.e. *rasa*, *rakta* and *sanghya*. *Rasavaha*, *Raktavaha* and *Sangyavahi* are the main *srotas* involved in *Madatyaya* and *srotodushti* is seen in the form of *sanga*. In this *vyadhi* *Haridya* (Heart) is the main *adhishthana*, due to which patient suffers from *ojakshaya*, *dhatukshaya*, *sharirkampa*, *pralapa*, *bhrama*, *agnivikriti* (*amavisha*), *anidra* and many more sign and symptoms of *madatyaya*. In the present study *Punarnavadi Ghritta* is selected because its constituents (*Punarnava*, *Yashtimadhu*, *Go-dugdha*, *Go-ghritta*) have *Tridosha shamaka* effects and increases *oja*, *bala*, *dhatu* by its *branhana* and *rasayana* effects.

Table No. 4 Probable mode of action of the drugs may be explained as follows

Drug	Rasa	Guna	Veerya	Vipaka	Doshaghanta	Karma
Punarnava (Mutaraladi varga)	Madhura, Tikta, Kasaya	Laghu, Ruksha	Ushna	Madhura	Tridosha shamaka	Deepana, Pachana, Anulomana, Mutral, Yakritutejaka, Shothhara, Vrishya, Rasayana, Raktavardhak
Yastimadhu (Chedanadi varga)	Madhura	Guru, Snigdha	Sheeta	Madhura	Vata-Pitta shamaka	Varnashotha, Medhya, Vatanulomak, Amlapitta, Raktavardhka, Shleshamahar, Rakta-pitta shamaka,
Go-dugdha	Madhura	Guru, Snigdha,	Sheeta	Madhura	Vata-Pitta shamaka	Rasayana, Medhya, Varnya, Pranadharaka, Mutrakriccha, Raktapitta

		Mridu,				and Jeernajwara nashaka,
Go-ghritta	Madhura	Guru, Snigdha	Sheeta	Madhura	Tridosha shamaka	Medhya, Rasayana, Veerya-Oja vardhak, Jwaranashaka, Urahkshata nashaka

*Punarnava - Tridosha shamaka*¹⁴

*Yashtimadhu - Vata-Pitta shamaka and Shleshmahara*¹⁵

*Go-dugdha - Vata-Pitta shamaka*¹⁶

*Go-ghritta - Tridosha shamaka*¹⁷

Madatyaya is a *Tridoshaja vyadhi*, and the contents of *Punarnavadi ghritta* have *Tridosha shamaka* effects. So it may also help in relieving the sign and symptoms of *Madatyaya*.

Discussion on Overall Effect of Therapy:

Out of 30 patients included in the study; the 3 (10%) patients shows marked improvement, 18 (60%) patients were moderately improved. There was no patient with mild relief during the trial. There were 9 (30%) patients with no relief.

According to the lab. Investigation of all the 30 patients the overall percentage improvement was 32.56%.

The study reveals that the 30 patients which were treated with "*Punarnavadi Ghritta*" showed significant relief in *Sweda, Prajagrana, Sharirkampa, Trishna* and *Aruchi* sign and symptoms. In laboratory investigations there was significant improvement in Hb gm%, TLC, ESR, SGPT, SGOT, Total Bilirubin, Direct Bilirubin, Indirect Bilirubin.

CONCLUSION

The trial drug *Punarnavadi Ghritta* act as a *rasayana* for the patients. As a *ghritta* preparation it is *yogavahi* and delivers it action on each and every cell of the body easily and more effectively. Its contents helps in removing toxins from the body, act as liver stimulant, brain tonic, *ojovardhaka, balya, dhatuwardhaka*. So, the trial drug can be used as effective medicine to improve sign symptoms of withdrawal symptoms in patients of *Madatyaya*.

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