

E ISSN 2350-0204

# IJAPC

**VOLUME 11 ISSUE 3 2019** 

www.ijapc.com Greentree Group Publishers (GGP))



#### Int J Ayu Pharm Chem

RESEARCH ARTICLE

www.ijapc.com

e-ISSN 2350-0204

### A Clinical Study to Evaluate the Efficacy of Vachadi Ghrita in the Management of Apasmara w.s.r. to Epilepsy

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#### **ABSTRACT**

**Objectives of the study:** To critically analyse the symptoms of *Apasmara*/ Epilepsy. To evaluate the effect of *Vachadi Ghrita* in *Apasmara*/Epilepsy. **Design of the Study-** Open labelled clinical study with pre and post test design. **Setting-** SDM Hospital Kuthpady, Udupi. **Study selection-** Twenty patients diagnosed as *Apasmara*/ Epilepsy are selected irrespective of their gender, caste and creed.

**Intervention-** Selected patients were treated with oral administration of *Vachadi Ghrita* in the dose of 24ml before food once a day early morning and same is continued for 28days with hot water as *Anupana*. **Results:** *Vachadi Ghrita* is effective in the remission of the symptoms of *Apasmara*/ Epilepsy as evidenced by statistically significant reduction in the symptom score of various subjective parameters. **Conclusion-**The different causative factors like *Aharaja*, *Viharaja*, *Manasika Nidana* causes morbidity of *Tridosha* which in turn increases *Rajas* and *Tamas* in the mind and produces *Apasmara* whose symptoms match with Epilepsy in parallel psychiatry. Oral medication by *Vachadi Ghrita* in a dose 24ml OD with hot water as *Anupana* was effective in the remission of signs and symptoms of *Apasmara*/ Epilepsy. Significant results were obtained for the ten mental factors involved in *Apasmara*/ Epilepsy along with its signs and symptoms. This improvement proved to be statistically significant.

#### **KEYWORDS**

Apasmara, Epilepsy, Manasa Bhava, Vachadi Ghrita



Received 06/08/19 Accepted 14/10/19 Published 10/11/19



#### **INTRODUCTION**

Ayurveda emphasizes that Sharira and Manas both interact with one another in all spheres of life. This approach towards health and disease is entirely psyachosomatic in its nature. Ayurveda mostly emphasizes on the phenomena of mind than that of the body. The concept of Manas were in ancient India since Prevedic Kala. In Vedas, it is mentioned that mind has been conceived to be the functional of element Atman (soul).Apasmara is included under Manasika Vikara in Ayurveda. In this disease Smriti Nasha and Sanja Nasha are the main symptoms, which are closely  $Manas^{1-2}$ . related The to commentary concerning the Apasmara or epileptic threshold and the epileptic probability of an individual in relation to the provocation of Manasika Dosha, are gaining vast prominence. Those opinions have been mentioned by the Acharyas in phrases of 'Upahata Chetas'. The treatment in the contemporary science, constructs assertive resistance on physiological actions conquer to pathological development, resulting in reluctant action by the body leading to various complications on physical and mental health. Inspite of hard curability, Ayurveda Shamana Chikitsa can give best

results with improving signs and symptoms, enhances quality of life to the patient in the society.

Epilepsy is a persistent non communicable disease of the brain that affects greater than 50 million humans worldwide. It is characterized by way of recurrent seizures, which are brief episodes of involuntary movement which could involve part of the body (partial) or the complete body (generalized) and are now and again observed by means of lack of recognition and manage of bowel or bladder feature.<sup>3</sup> The *Rasayan*<sup>4</sup> has been held in high esteem for its beneficial effects in the chronic and unresponsive conditions and have been strongly recommended in the condition of Apasmara. Sodhana is indicated as the first line of treatment. The drug, Vachadi Ghrita fulfills almost all the criteria of principles of treatment of Apasmara and has been advocated to use in all the important texts. Inspite of such a high reputation, till now no clinical study has beenconducted on it. Hence, selecting VachadiGhrita for study holds great relevance.

In the present study, 20 patients of *Apasmara/* Epilepsy were treated in single group with *Vachadi Ghrita* for 28 days and follow up after 28 days. The results were effective on different stages of *Apasmara/* Epilepsy. However, *Vachadi Ghrita* provided better improvement in *Samanya* 



Lakshana of Apasmara/ Epilepsy, the features of the ictal stage along with, the Dushti Laksanas during both ictal and postictal stages. The frequency of attacks and the duration of attacks were reduced considerably after the course of treatment. There was reduction in the severity of the disease also. The follow-up observation indicated further decrease in frequency of seizures along with improvement in the seizure threshold.

#### **MATERIALS AND METHODS**

**STUDY DESIGN:** Open labelled clinical study with pre and post test design.

#### SOURCE OF DATA

Minimum 20 patients with a definite diagnosis of fulfilling the diagnostic, inclusion criteria of *Apasmara* were selected for the study irrespective of sex, caste and religion from the OPD and IPD of SDMAH, Udupi.

#### **DIAGNOSTIC CRITERIA**

- 1. Samanya Lakshana of Apasmara mentioned in Ayurvedic texts. <sup>5,6,7</sup>
- <sup>2.</sup> Clinical features of Epilepsy by International League against Epilepsy (ILAE)<sup>8</sup>

#### **INCLUSION CRITERIA**

- 1. 16 to 70 years of age.
- 2. On irregular medications and irrespective of discrimination of race,

religion/caste and gender were eligible for the study.

- 3. Frequency of attack less than 3 months
- 4. Patient who are not benefitted by taking other medicines, will be included without disturbing their regular medicines.
- 5. Patients who agreed to sign the consent form.

#### **EXCLUSION CRITERIA**

- Patients with diabetes mellitus, hypertension, congenital abnormalities
- 2. Mental retardation, infectious diseases of brain, vascular causes, toxic causes and metabolic causes of seizures.

#### ASSESSMENT CRITERIA:

The assessment was done by using self prepared scale on *Manasika Bhavas* of *Apasmara Lakhshana* and scale of Ictal features of epilepsy on 0<sup>th</sup>, 28<sup>th</sup> and 56<sup>th</sup> of the study and the statistical analysis of pre and post trial was done by paired 't' test.

#### **PARAMETERS**

- 1. Self-prepared scale on *Manasika bhava*.
- 2. Scale for ictal features of epilepsy.
- I. Severity of attack
- II. Frequency of attack
- III. Duration of attack
- 3. Self assessment scale for the symptoms of Apasmara.

#### **INTERVENTION**

Twenty patients of *Apasmara*/ Epilepsy who fulfilled the diagnostic and inclusion criteria were treated in a single group.



Administrating *Vachadi Ghrita* orally 24gms, with hot water at 8.00AM before food for 28 days.

Dose: For Shamana, Ghrita Matra 24gms.

**Follow Up:** Follow up was done after 28 days of the treatment.

**Total duration of study:** 56 Days

Ethical committee clearance number-SDMCAU/ACA-49/ECA80/16-17.

#### **INVESTIGATIONS**

CBC, urine routine, serum electrolyte, fasting lipid profile ,EEG, ECG, CT, and MRI were done in needed cases. Animal study was not conducted.

#### **Drug Review**

The following are the ingredients of *Vachadi Ghrita*<sup>9,10</sup>

Kalka Dravyas:

- 1. 1.Vacha
- 2. 2.Shampaka (Aragvadha)
- 3. 3. Kaitarya(Katphala)
- 4. 4. Vayastha (Guduchi)
- 5. *5.Hingu*
- 6. 6. Choraka
- 7. 7. Palankasha (Guggulu)
- 8. 8. GoGhrita
- 9. 9. Jala

#### **RESULTS**

The results were statistically analysed using paired 't' test. The each criteria in the scale used, were having mild improvement. On overall analysis of results, improvement in Samanya Lakshana of Apasmara was 25.94%, improvement in Manasa Bhava rating scale was 41 %, improvement in severity of attack rating scale was 27.97%, improvement in frequency of attack rating scale was 35.71%, improvement in duration of attack rating scale was 23.53%, improvement in pre-ictal features rating scale was 41.18%, improvement in ictal rating scale features was 34.64%, improvement in post-ictal features rating scale was 33.87%. All the results showed statistically highly significant results with p value < 0.001.

#### DISCUSSION

#### Effect of Vachadi Ghrita on Samanya Lakshanas of Apasmara

The patients treated with *Vachadi Ghrita* had reduction in symptoms. After treatment of 28 days, the initial mean score 11.95 of *Samanya Lakshana* was reduced to 8.85 with 25.94% improvement which was statistically highly singnificant (P <0.001). In *Samanya Lakshanas* of *Apasmara Ayurveda* explains that it is a *Manasa* related *vikara* and in *Apasmara Samprapti*, *Manas* is mostly affected during the *Vegaavastha*, and features like *Hridgraha*, *Patana*, *Hastapada Viskhepa*, loss of consciousness etc. like symptoms are produced. So with the administration of



Vachadi Ghrita which contains Medhya Dravyas, we found improvement in

Samanya Lakshana of Apasmara during the study duration.(Table- 1)

Table 1 Effect of VachadiGhrita on SamanyaLakshana of Apasmara

SLA	MEAN	V		PAIRED 't' T	EST				
	BT	AT	BT- AT	%OF IMPROVEM ENT	SD	SEM	MEDIAN	ʻt' VALUE	P VALUE
UGR& SPSS	11.95	8.85	3.1	25.94%	BT-4.559	BT-1.019	BT-10.000	4.905	<0.001
					AT-3.843	AT-0.859	AT-7.000	_	

# Effect of *Vachadi Ghrita* on severity of attack of epilepsy

The patients treated with Vachadi Ghrita had reduction in severity of attack. The initial mean score of 2.150 was reduced to 1.550 with 27.97% improvement which was statistically highly significant (P <0.001). By these observations, it is clear that the Vachadi Ghrita in Shamana form is reducing the severity attack. Even the studies on ketogenic diet by David Goldenberg, describes that ketogenic materials are helpful in reducing the seizure activity. Ketogenic diet is low carbohydrate and high fat diet so is the Vachadi Ghrita. In modern science Ketogenic diet is prescribed for epilepsy, and was proposed in the 1920s and has produced variable clinical responses. Although the mechanism involved in the ketogenic diet is not clear, the main effects of the ketone bodies appear to be modulation neurotransmitter and antioxidant effects on the brain. Past studies shown that the mechanisms have underlying seizure control of ketone bodies are by fatty acid oxidation. This highlights the effect of the ketogenic diet on the modulation of neurotransmitters, levels and quantity of biogenic monoamines and protective antioxidant process of neurons.

While administering *Shamana Sneha*, explicit diet was followed that was less in carbohydrates, which facilitates further more reduction in the severity of seizure attack. *Ghrita* additionally pacifies *Vata & Rajodosha*, that are answerable for the manifestation of seizures (*BibhatsaChesta*) in *Apasmara*.(Table-2)

Table 2 Effect of VachadiGhrita on Severity of Attack of Epilepsy

SEVERITY	MEA	AN		PAIRED 't' TEST					
OF ATTACK	BT	AT	BT- AT	%OF IMPROVEMENT	SD	SEM	MEDIAN	ʻt' VALUE	P VALUE
					BT-1.040	BT-0.233	BT-2.000		
UGR& SPSS	2.1 50	1.55 0	0.6	27.97%	AT-0.887	AT-0.198	AT-1.500	5.339	<0.001



# Effect of Vachadi Ghrita on frequency of attack of epilepsy

The patients treated with *Vachadi Ghrita* had reduction in frequency of attack. The initial mean score 2.100 of Frequency of attack was reduced to 1.350 after the 28 days of treatment with 35.71% improvement which was statistically highly

significant (P <0.001). Due to aggravation of *Manasika Dosha* and its influence on *Vata Dosha*, there occurs repeated attacks. As *Vachadi Ghrita* controls the *Manasika Doshas* & is pleasant *Vata Shamaka*, the long term use of *Ghrita* may prove extremely beneficial in reducing the frequency of attacks.(Table-3)

Table 3 Effect Of VachadiGhrita On Frequency Of Attack Of Epilepsy

Table 5 Effect O	1 vacnaa	ionina c	m i icqu	ency of rittae.	k Of Lpn	срзу			
FREQUENY	MEAN			PAIRED 't	' TEST				
OF ATTACK	BT	AT	BT-	%OF	SD	SEM	MED	't'	P VALUE
			AT	<b>IMPROV</b>			IAN	VALUE	
				<b>EMENT</b>					
					BT-	BT-	BT-		
UGR & SPSS	2.100	1.350	0.75	35.71%	0.718	0.161	2.000	6.097	< 0.001
					AT-	AT-	AT-	_	
					0.745	0.167	1.000		

# Effect of Vachadi Ghrita on duration of attack of epilepsy

The patients treated with *Vachadi Ghrita* had reduction in duration of attack. The

initial mean score 1.700 was reduced to 1.300 after the treatment with 23.53% improvement which was statistically significant (P < 0.008). (Table-4)

Table 4 Effect Of VachadiGhrita On Duration Of Attack Of Epilepsy

Tuble I Effect of 7	cicricicii	minu On	Daran	on or rittaek	Of Epine	P <sup>o</sup> J			
DURATIONOF	MEAN	ſ		PAIRED 't	' TEST				
ATTACK	BT	AT	BT-	%OF	SD	SEM	MED	't'	P VALUE
			AT	<b>IMPROV</b>			IAN	VALUE	
				<b>EMENT</b>					
					BT-	BT-	BT-		_
UGR & SPSS	1.700	1.300	0.4	23.53%	0.979	0.219	1.000	2.990	0.008
					AT-	AT-	AT-	_	
					0.657	0.147	1.000		

By these observations, it can be inferred that although there was reduction in duration of attack in total it showed mild improvement only. The period of attack is shorter in *Vataja* and *Pittaja* as compared to *Kaphaja* variety of *Apasmara*.

# Effect of *Vachadi Ghrita* on pre-ictal features of epilepsy

The patients treated with *Vachadi Ghrita* had reduction in pre ictal features of epilepsy. The initial mean score 22.70 of pre-ictal features was reduced to 13.35 after the treatment, with 41.18% improvement which was statistically highly significant (P <0.001).(Table-5)



**Table 5** Effect of *Vachadi Ghrita* on pre-ictal features of Epilepsy

					1 1 /				
PRE-ICTAL	MEAN			PAIRED 't	' TEST				_
FEATURES	BT	AT	BT-	%OF	SD	SEM	MEDIA	't'	P
			AT	<b>IMPROV</b>			N	VALUE	VALUE
				<b>EMENT</b>					
					BT-	BT-	BT-		
UGR & SPSS	22.70	13.35	9.35	41.18%	7.706	1.723	21.000	13.274	< 0.001
					AT-	AT-	AT-	_	
					6.002	1.342	13.000		

# Effect of Vachadi Ghrita on ictal features of epilepsy

The patients treated with *Vachadi Ghrita* had reduction in ictal features of epilepsy. The initial mean score 17.90 before the treatment, was reduced to 11.70 after the treatment, with 34.64% improvement

which was statistically highly significant (P <0.001). As all the ingredients present in *Vachadi Ghrita* are *Medhya*,it shows more improvement in ictal features of epilepsy. Mostly improvement in symptoms like loss of consciousness, convulsive movements and memory loss were obtained (Table-6).

**Table 6** Effect of *VachadiGhrita* on ictal features of Epilepsy

Tuble o Effect o.	1 racmaa	i Omina C	m ictui i	reatures or Ep	перву				
ICTAL	MEAN	-		PAIRED 't	' TEST				
<b>FEATURES</b>	BT	AT	BT-	%OF	SD	SEM	MEDIA	ʻt'	P VALUE
			AT	<b>IMPROV</b>			N	VALUE	
				<b>EMENT</b>					
					BT-	BT-	BT-		
UGR & SPSS	17.90	11.70	6.2	34.64%	6.766	1.513	18.500	11.070	< 0.001
					AT-	AT-	AT-	_	
					4.953	1.108	12.000		

# Effect of Vachadi Ghrita on post-ictal features of epilepsy

The patients treated with *Vachadi Ghrita* had reduction in post ictal features of epilepsy. The initial mean score 9.300 was reduced to 6.150 after the treatment, with

33.87% improvement which was statistically highly significant (P <0.001). There was improvement in headache, irritability, body ache and automatism after the intervention with *Vachadi Ghrita* in *Apasmara* patients. (Table-7)

**Table 7** Effect of *Vachadi Ghrita* on post ictal features of Epilepsy

POST		MEAN		-	PAIRED 't					
ICTAL	DEC	BT	AT	BT-	%OF	SD	SEM	MEDI	ʻt'	P VALUE
FEATU	KES			AT	IMPROV EMENT			AN	VALUE	
					LIVILIVI	BT-	BT-	BT-		_
UGR	&	9.300	6.150	3.15	33.87%	3.213	0.719	9.000	7.112	< 0.001
SPSS						AT-	AT-	AT-	_	
						2.207	0.494	5.000		

Effect of Vachadi Ghrita on Manasa Bhavas Manasa Bhava includes Samnja (consciousness), orientation, Buddhi



(intelligence), Smriti (memory) & Achara (behaviour). These can get hampered in chronic cases of epilepsy or seizure disorder. Specific Gunas like Smriti Vardhaka, Medhya, Swapna, etc are assigned to Vachadi Ghrita. Cow's ghee processed with Medhya dravyas is considered to be one of the most important medicine for Apasmara or any other

psychiatric disorders. In this study we observed that *Manasa Bhava* showed significant improvement as all the drugs present in the *Vacahdi Ghrita* are *Medhya*.(Table-8,9)

 Table 8 Overall effect of the treatment

Overall	No of	% Of
effect	<b>Patients</b>	improvement
Unchanged	0	0
Mild	20	100%
Improvement		

**Table 9** Effect of the treatment on each criteria

ASSESSMENT CRITERIA		% OF IMPROVEMENT
SamanyaLakshana Of Apasmara		25.94%
Severity Of Attack		27.97%
Frequency Of Attack		35.71%
Duration Of Attack		23.53%
Pre Ictal Features		41.18%
Ictal Features		34.64%
Post Ictal Features		33.87%
	Intensity	34.04%
Mano Vibhrama	Frequency	38.24%
	Intensity	31.82%
BuddhiVibhrama	Frequency	11.76%
	Intensity	42.11%
SanjnaJnanaVibhrama	Frequency	45.83%
	Intensity	30%
SmritiVibhrama	Frequency	47.83%
	Intensity	40.74%
Bhakti Vibhrama	Frequency	54.55%
	Intensity	33.33%
SheelaVibhrama	Frequency	70.59%
	Intensity	31.25%
VachikaCheshtaVibhrama	Frequency	41.67%
	Intensity	58.82%
SharirikaCheshtaVibhrama	Frequency	53.85%
	Intensity	27.78%
AcharaVibhrama	Frequency	31.25%
	Intensity	48.49%
SwapnaVibhrama	Frequency	45.83%

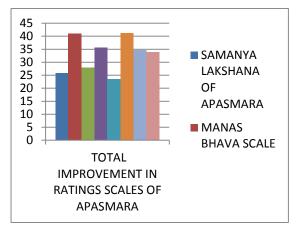
# Discussion on probable mode of action of Vachadi Ghrita

The *Rasayana* effect of *Vachadi Ghrita* may play main role. Its action may be explained on the basis of science that the drug accelerates the rate of sugar transport.

It is proposed that the antiepileptic effect of medicines is due to the increase in brain glucose. There is a general opinion that medicines depress the activity of the nervous system and much more glucose is left behind simply because not quite so



much is being metabolised. But it may not be happens. There is enough evidence that the drug at the doses used to prevent epilepsy do not depress the metabolic activity of the brain, but depress any elevation in activity usually associated with convulsions. Therefore, the elevation in brain glucose is not simply due to lack of metabolism but due to increased transport. By affecting the water molecules of the cell structures, it might be possible to give it a stiffer structure and alter the tendency of ions of sodium and potassium (which are involved in determining the membrane potential) to move across the membrane in such a way that it is difficult to depolarise the cell, difficult to cause a seizure. There is also the possibility that the extra more the activities glucose alter neurotransmitters of the brain. In this way severity, duration, frequency of ictal phase of epilepsy improved.



**Graph 1** Total improvement in ratings scale of Apasmara

#### **CONCLUSION**

In this clinical study, 20 patients having the signs and symptoms of *Apasmara* /Epilepsy In clinical study patient may get relief or may not be get relief. The study can ends with giving positive or negative results. After giving *Ghrita* preparation patients 41% improvement in Manasa Bhavas, because Ghrita and the ingredients are especially acts as *Medhya*,so is considered as MedhyaRasyana. By which quality of life of the patients also enhances. Even though result obtained is differs from patient patient concluded that Vachadighrita have significant effect in improving the sufferings of disease Apasmara. Henceit is evident to improve the quality of health too. Thus observations observed in 20 patients are given below:



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