

AN OPEN LABELLED CLINICAL TRIAL ON THE EFFECT OF UNMADA GAJA KESARI RASA IN KAPHAJA UNMADA W.S.R. TO DEPRESSION

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ABSTRACT

Throughout the ages emotions have mastered the life of human being. The slight aberrations of emotions if prolonged can become a concern. Depression is a mood disorder which affects 121 million people worldwide.

Objective: To evaluate the therapeutic efficacy of *Unmadagajakesari* rasa in *KaphajaUnmada* /Depression.

Design of the study: An open label clinical study with pre and post test design. **Materials and Methods:**

Source of data: 20 patients diagnosed as *KaphajaUnmada* (Depression) fulfilling the Diagnostic and Inclusion criteria were selected from OPD/IPD of SDM College of Ayurveda & Hospital, Udupi, Karnataka.

Intervention: Oral medication Tab. *Unmadagajakesari* rasa was administered in a dosage of 250mg twice a day for 28 days. **Main outcome measures:** percentage changes in the symptoms including Hamiltons depression rating scale. **Results:** The statistical analysis was done by Student's Paired 't' test and the result obtained were highly significant(p<0.001). In overall improvement of patients, 95% patients had marked improvement and 5% patient had excellent improvement. **Conclusion:** The result affirms the therapeutic benefit of *Unmadagajakesari* rasa in *kaphajaunmada*.

Keywords: *Kaphajaunmada*, Depression, *Vibhrama*, *Unmadagajakesari* Rasa

INTRODUCTION

Kaphajaunmada has prototypical manifestations of depression. The World Mental Health Survey conducted in 17 countries found that on average about 1 in 20 people reported having an episode of depression in the previous year.¹ Depressive disord-

ers often start at a young age; they reduce people's functioning and often are recurring. Considering this the present study has been carried out to obtain maximum benefit to mankind.

Manifestation pertaining to eight derangements listed as derangement of thoughts, disruption in professional performance, disorganization in consciousness, reluctance towards personal interests, emotional commotion, corrugation of speech, distressed physical activities, disconcerted conduct are the abnormalities that ensure the diagnosis. Thus results in impairment of personal, social, occupational and other important areas of life.

*Unmada*² is defined as the disruption of *manas* and other higher faculties like *buddhi*, *samjnanana*, *smriti*, *bhakti*, *sheela*, *cheshta* and *achara*. *Kaphaja Unmada*, one among the five types of *Nijaunmada* described in the literature, share a lot of similarities with Depression.

Depression is a diseased condition in which the person's mood is affected and symptoms like depressed mood and pessimism, increased fatigability, reduced energy, loss of interest and enjoyment are present along with other symptoms such as reduced attention and concentration, poor self-esteem, self-difference, ideas of guilt and unworthiness, loss of appetite, sleep disturbances and ideas of self harm.³

The uniqueness of herbo-mineral drug lies in binding different varieties of drugs into a complex structure and its exclusive effect. Various trial studies showed that *Vacha*⁴ and *Brahmi*⁵ possess obvious antidepressant effects. A *rasaushadhi* named *Unmadagajakesari rasa*⁶ has been chosen for shaman medication which possess *Kajjali*, *Manashila*, *Daturametel*, *Acoruscalamus*, *Bacopamonieri* which are mainly *kaphavata shamaka*, *medhya*, *rasayana*, *unmadahara* in quality. The trial drug has easily accessible ingredients, cost effective and easily administrable without hospitalization.

Objectives of Study:

To evaluate the therapeutic efficacy of *Unmadagajakesari rasa* in *Kaphaja Unmada* (Depression).

Materials and methods:

Source of data: 20 patients diagnosed as *Kaphaja Unmada* (Depression) fulfilling the Diagnostic and Inclusion criteria were selected from OPD/IPD of

SDM College of Ayurveda & Hospital, Udipi, Karnataka, India.

Drug:

Each tablet of 250 mg of *Unmadagajakesari rasa* were procured from SDM Ayurveda Pharmacy, Udipi. The drug contained *parada*, *gandhaka*, *manashila*, *datura* processed with *vacha* and *brahmiswarasa*.

Method of collection of data:

A special Proforma was prepared with all points of history taking, physical signs and symptoms of Ayurveda and allied science. Laboratory investigations were carried out as mentioned in Allied sciences. Selected patients were subjected to detailed clinical history and complete examination. The patients satisfying the entire norms were taken for the study.

Design of the study:

An open label clinical study with pre and post test design - Minimum twenty patients diagnosed as *Kaphaja Unmada* (Depression) were selected irrespective of their gender, caste and creed. Investigations and the parameters of signs and symptoms were recorded, scored accordingly and analyzed statistically by adopting the Student's paired T-test.

Intervention:-

Oral medication Tab. *Unmadagajakesari rasa* was administered in a dosage of 250mg twice a day for 28 days.

Duration of study: 28 days

Diagnostic Criteria:

1. *Lakshana* of *Kaphaja Unmada* as per Ayurveda Classics.
2. Criterion of Depression in ICD-10⁷

Inclusion criteria-

1. Patients fulfilling diagnostic criteria
2. Both sexes between the age group 16-70 years

Exclusion criteria

1. Patients of other *Nija Unmada* and *Bhutonmada*.
2. Diagnosed case of Schizophrenia, Schizophrenic form of Disorder.
3. Patients suffering from any other psychotic disorders.

Assessment criteria:

1. Relief in the symptomatology of *kaphajaunmada*
2. The Hamilton Rating Scale for depression⁸

Observation-

Out of 20 patients of *kaphajaunmada* taken for this study, highest of 30% belongs to the age group of 21-30 years. 50 %each were of male and female gender. 85 % of patients belong to Hindu religion. 55% patients were married. The study revealed that 55% of the patients belongs to the lower middle socio-economic status, 35% completed graduation, 35% patients were House wives. 80% patients had mixed diet and 95% had *vishamashana*. 70% patients had no addictive habits. 95% had gradual onset and 80% had progressive course of illness. Maximum of 40% patients had illness from 2 to 5 years duration. 85% patients had no history of psychiatric illness in the family. 80% patients of this study were belonging to the mixed diet category. 95% patients had *mandhaagni*. 65% patients had sedentary work and 35% patients were manual workers. 95% patients reported disturbed sleep. 35% patients had satisfied relationship with spouse. All the patients belong to *Dvandvajapra-kruiti*. 15% patients belong to *pravara-pramana*. The assessment of *sara* in this study showed maximum number of patients having *madhyamasara* i.e. 70%. 65% of the patients showed *madhyamasamhanana* and 80% patients had *avarasatmya*. All the 100% patients belong to *avarasatwa*, *madhyamavaya* and *avaraaharashakti* and 85% patients had the *avaravyayamashakti* in this study.

It was observed that all the 100% patients taken for this study had depressed mood, retardation in personal and professional activities. 95% patients had psychomotor retardation, loss of confidence or self esteem .90% of them had symptom of insomnia and symptoms of suicidal ideation. 80% patients had reduced physical movements. 55% patients had altered sexual habits. Out of 20 patients in the study, all 20 patients showed derangements of thoughts, professional activities, memory, temperaments, emotions, behaviours, speech, sleep ha-

bits and physical symptoms of *kaphajaunmada*. In assessment of The Hamilton Rating Scale for depression only 15% patients had altered levels of consciousness. All 100% patients showed symptoms of depressed mood, feelings of guilt, suicidal thoughts, insomnia middle, altered work and activities, anxiety (psychological), somatic symptoms (gastrointestinal), somatic symptoms (general) of different grades. 95% patients showed symptoms of insomnia early, symptoms of anxiety (somatic), altered psychomotor activities and diurnal variation, 90% patients had insomnia late of different grades. 70% patients had genital symptoms, 15% had hypochondriasis, 35% had loss of weight, 10% had disturbances of insight, 5% patient had obsessional and compulsive symptoms. No patient had depersonalization or paranoid symptoms.

Results-

The study proved that there was improvement of 59.51% in *manovibhrama*, 53.93% in *buddhivibhrama*, 47.22% in *samnjajnavibhrama*, 50% in *smrithivibhrama*, 60.5% in *bhakthivibhrama*, 58.56% in *sheelavibhrama*, 58.23% in *vakcheshtavibhrama*, 60.43% in *shareeracheshtavibhrama*, 60.49% in *acharavibhrama* and 69.38% in *swapnaviparyaya*. P value was statistically significant as it was $p < 0.083$ for *samnjajnana* and $p < 0.001$ for all other *vibhrama*. There was improvement of 57.14% in Depressed Mood, 62.79% in Feelings Of Guilt, 68.42% in Suicide Ideation, 89.18% in Insomnia Early, 96.42% in Insomnia Middle, 84.84% in Insomnia Late, 62.90% in Work And Activities, 78.57% in Psychomotor Retardation, 77.77% in Agitation, 66.66% in Anxiety (Psychological), 52.94% in Anxiety Somatic, 57.57% in Somatic symptoms (Gastrointestinal), 48.48% in Somatic Symptoms General, 22.22% in Genital Symptoms, 71.42% in Hypochondriasis, 85.71% in Loss Of Weight, 100% in Insight, 75.75% in Diurnal Variation And 65.38% in Diurnal Variation Severity.

DISCUSSION

Dietary habits, life style modalities, emotional quotient, environmental stress plays a major role in the causation of *unmada*. Also the morbidity of *shareerikadosha* which perturbs the *manodosha* can cause different other serious diseases in different systems. The symptoms of *kaphajaunmada* including *unmadasamanyapoorvaroopa* and *samanyaroopa*, the assessment of patient is possible in this study with a self prepared diagnostic tool. The drug in the formulation *unmadagajakesari rasa* is *kaphavatashamaka*, *medhya*, *rasayana*, *unmadahara* in quality. The formulation is easily administrable, does not require hospitalization and cost effective too. The *medhyarasayanaBrahmi*⁵ and *Vacha*⁴ are used as *bhavanadravya* here. These both increase the efficacy of the drugs in the formulation enormously. The ghee is used as *anupana* here which is *medhya*. Thus the formulation in total clears the accumulation of *kapha* and *tamodosha* which causes *unmada* along with imbibing *rasayana* quality. And it also increases the *medha* of person by its *prabhava*. Excellent improvements were seen in all the criteria. The criteria like depressed mood, reduced interests, *swapnavibhrama* and insomnia late have very good improvements. The formulation had better result in the complaints of irregularity of sleep. There were drastic changes in the result of *shaareerikalakshana* of *kaphajaunmada* scale. It may be that the somatic symptoms of psychological origin have been reduced dramatically during treatment.

The overall assessment of *unmadagajakesari rasa* on *kaphajaunmada* showed 59.59% of improvement in *kaphajaunmada* scale and 69.69% of improvement is Hamilton depression rating scale. The improvements of each criteria in the scale used is having remarkable changes. In overall improvement of patients, maximum of 19 patients had marked improvement and 1 patient had excellent improvement.

CONCLUSION

There was considerably remarkable result on eight mental factors involved in *kaphaja unmade* along with signs and symptoms. Impressive changes in final results are noted as over all assessment of *kaphajaunmada* scale showed 59.59% of improvement and 69.69% of improvement in Hamilton depression rating scale. This improvement confirms that *unmadagajakesari rasa* has attenuating effect in *kaphajaunmada*. Further the symptoms like depressed mood, sleep disturbances, psychomotor retardation were treated effectively. Hence it can be said that *unmadagajakesari rasa* can be prescribed as an effective treatment in *kaphajaunmada/ depression*.

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Tables and illustrations-

Table 1: Effect of *vibhrama*

Effect of <i>manovibhrama</i> intensity	Mean		Difference in Means	Percentage Improvement	Paired 't' Test			
	BT (±SE)	AT (±SE)			S.D.	S.E.M	't'	P
	3.000 (0.192)	0.950 (0.114)	2.050	68.33%	0.686	0.153	13.358	<0.001
<i>Mano vibhrama</i> frequency	3.550 (0.135)	1.750 (0.123)	1.800	50.70%	0.616	0.138	13.077	<0.001
<i>Buddhivibhrama</i> intensity	2.300 (0.263)	1.050 (0.135)	1.250	54.3%	0.967	0.216	5.784	<0.001
<i>Buddhivibhrama</i> frequency	2.800 (0.247)	1.300 (0.128)	1.500	53.57%	0.827	0.185	8.110	<0.001
<i>Samjnajanavibhrama</i> intensity	0.300 (0.164)	0.150 (0.0819)	0.150	50%	0.366	0.0819	1.831	0.083
<i>Samjnajanavibhrama</i> -frequency	0.450 (0.256)	0.250 (0.143)	0.200	44.44%	0.523	0.117	1.710	0.104
<i>Smrithivibhrama</i> intensity	1.600 (0.152)	0.800 (0.117)	0.800	50%	0.410	0.0918	8.718	<0.001
<i>Smrithivibhrama</i> frequency	2.200 (0.236)	1.100 (124)	1.100	50%	0.852	0.191	5.772	<0.001
<i>Bhaktivibhrama</i> intensity	3.000 (0.192)	1.100 (0.100)	1.900	63.3%	0.788	0.176	10.782	<0.001
<i>Bhaktivibhrama</i> frequency	2.85 (0.196)	1.200 (0.117)	1.650	57.89%	0.988	0.221	7.468	<0.001
<i>Sheelavibhrama</i> intensity	3.050 (0.114)	1.150 (0.0819)	1.900	62.29%	0.641	0.143	13.262	<0.001
<i>Vachikacheshta vibhrama</i> intensity	2.950 (0.135)	1.200 (.0918)	1.75	59.32%	0.550	0.123	14.226	<0.001
<i>Vachikacheshtavibhrama</i> frequency	3.150 (0.196)	1.350 (0.109)	1.800	57.14%	0.834	0.186	9.658	<0.001
<i>Shareecheshtavibhrama</i> intensity	2.450 (0.153)	0.950 (0.114)	1.500	61.22%	0.688	0.154	9.747	<0.001
<i>Shareecheshtavibhrama</i> frequency	2.850 (0.221)	1.150 (0.131)	1.700	59.64%	0.865	0.193	8.974	<0.001
<i>Acharavibhrama</i> intensity	2.650 (0.182)	1.100 (0.124)	1.550	58.49%	0.605	0.135	11.461	<0.001
<i>Acharavibhrama</i> frequency	2.800 (0.213)	1.050 (0.135)	1.750	62.5%	0.639	0.143	12.254	<0.001
<i>Swapnaviparyaya</i>	2.400	0.600	1.800	75.00%	0.696	0.156	11.658	<0.001

intensity	(0.169)	(0.112)						
Swapnaviparyaya frequency	3.450 (0.135)	1.250 (0.160)	2.200	63.76%	0.951	0.213	10.341	<0.001
Shareerikalakshana	3.850 (0.357)	0.200 (0.117)	3.650	94.80%	1.663	0.372	9.815	<0.001

Table 2: Effect on symptoms of depression

Effect on symptoms	Mean		Difference in Means	Percentage Improvement	Paired 't' Test			
	BT (±SE)	AT (±SE)			S.D	S.E.M	't'	P
Depressed mood	2.450 (0.135)	1.050 (0.0881)	1.400	57.14%	0.503	0.112	12.457	<0.001
Feelings of guilt	2.150 (0.131)	0.800 (0.0918)	1.350	62.79%	0.489	0.109	12.337	<0.001
Suicidal thoughts	2.850 (0.182)	0.900 (0.0688)	1.950	68.42%	0.605	0.135	14.419	<0.001
Insomnia early	1.850 (0.136)	0.200 (0.0723)	1.650	89.18%	0.587	0.131	12.568	<0.001
Insomnia middle	1.400 (0.169)	0.500 (0.050)	1.350	96.42%	0.745	0.167	8.102	<0.001
Insomnia late	1.650 (0.150)	0.250 (0.0993)	1.400	84.84%	0.754	0.169	8.304	<0.001
Work and activities	3.100 (0.176)	1.150 (0.0819)	1.950	62.90%	0.759	0.170	11.487	<0.001
Psychomotor retardation	1.400 (0.169)	0.300 (0.105)	1.100	78.57%	0.447	0.100	11.00	<0.001
Agitation	0.900 (0.161)	0.200 (0.0918)	0.700	77.77%	0.470	0.105	6.658	<0.001
Anxiety psychological	3.450 (0.135)	1.150 (0.0819)	2.300	66.66%	0.571	0.128	18.006	<0.001
Anxiety somatic	1.700 (0.231)	0.800 (0.156)	0.900	52.94%	0.718	0.161	5.604	<0.001
Somatic symptoms (gastrointestinal)	1.650 (0.109)	0.700 (0.105)	0.950	57.57%	0.510	0.114	8.324	<0.001
Somatic symptoms (general)	1.650 (0.109)	0.850 (0.109)	0.800	48.48%	0.616	0.138	5.812	<0.001
Genital symptoms	0.900 (0.161)	0.700 (0.105)	0.200	22.22%	0.410	0.0918	2.179	0.042
Hypochondriasis	0.350 (0.196)	0.100 (0.100)	0.250	71.42%	0.639	0.143	1.751	0.096
Loss of weight	0.350 (0.109)	0.050 (0.050)	0.300	85.71%	0.470	0.105	2.854	0.010
Insight	0.100 (0.0688)	0.00 (0.00)	0.100	100%	0.308	0.0688	1.453	0.0163
Diurnal variation	1.650 (0.131)	0.400 (0.112)	1.250	75.75%	0.55	0.123	10.162	<0.001
Diurnal variation severity	1.300 (0.128)	0.450 (0.114)	0.850	65.38%	0.489	0.109	7.768	<0.001

Table 3: Rating scale for *KaphajaUnmada*

1. Manovibhrama			
Intensity of thought abnormality		Frequency of thought abnormality	
a. Thought content is normal	0	a. Never	0
b. Decreased new interest	1	b. Occasional	1
c. Feeling like I can't do anything right	2	c. Sometimes	2
d. Future has nothing positive for myself /hopelessness	3	d. Frequently	3
e. Severe worthless thoughts about oneself and world	4	e. Constantly	4
2. Buddhivibhrama			
Intensity of intellect abnormality		Frequency of intellect abnormality	
a. Normal professional performance	0	a. Never	0
b. Minor error and correct by himself	1	b. Occasional	1
c. Major errors, needs support from the colleagues	2	c. Sometimes	2
d. Major error, needs continuous supervisions	3	d. Frequently	3
e. Cannot continue the professional work	4	e. Constantly	4
3. SamjnaVibhrama			
Intensity of consciousness / orientation abnormality		Frequency of consciousness/ orientation abnormality	
a. Normal self esteem / orientation	0	a. Never	0
b. Oriented in ward	1	b. Occasional	1
c. Misidentifies	2	c. Sometimes	2
d. Obvious disorientation during most of the interview	3	d. Frequently	3
e. Stuporous most of the times	4	e. Constantly	4
4. Smriti vibhrama			
Intensity of erratic memory		Frequency of erratic memory	
a. Adequate and complete memory	0	a. Never	0
b. Forgetfulness of some events	1	b. Occasional	1
c. Forgetfulness of daily routine	2	c. Sometimes	2
d. Long term memory loss	3	d. Frequently	3
e. Complete memory loss	4	e. Constantly	4
5. BhaktiVibhrama			
Intensity of erratic personal interests		Frequency of erratic personal interests	
a. Normal inclination /aversion	0	a. Never	0
b. Decreased inclination towards commodities	1	b. Occasional	1
c. Aversion towards commodities cannot be curtailed	2	c. Sometimes	2
d. Lack of interest towards some commodities	3	d. Frequently	3
e. Complete aversion toward acquiring commodities	4	e. Constantly	4
6. SheelaVibhrama			
Intensity of erratic mood		Frequency of erratic mood abnormality	
a. Normal participation/ avoidance of past time activity	0	a. Never	0
b. Decreased participation, self confident	1	b. Occasional	1
c. Aversion in participation	2	c. Sometimes	2
d. Markedly decreased mood	3	d. Frequently	3
e. Complete absence of participation	4	e. Constantly	4
7. VachikaCheshtaVibhrama			
Intensity of abnormal speech		Frequency of abnormal speech	
a. normal speech	0	a. Never	0

b. relevant/ delayed speech	1	b. Occasional	1
c. decreased amount of speech	2	c. Sometimes	2
d. lack of desire for speech	3	d. Frequently	3
e. complete absence of speech	4	e. Constantly	4
8. Sharirikacheshavibhrama			
Intensity of abnormal motor activity		Frequency of abnormal motor activity	
a. Relevant motor activity	0	a. Never	0
b. Subjectively decreased movements	1	b. Occasional	1
c. Lack of energetic movements	2	c. Sometimes	2
d. Hypoactive movements	3	d. Frequently	3
e. Complete absence of movements	4	e. Constantly	4
9. AcharaVibhrama			
Intensity of abnormal mannerism		Frequency of abnormal mannerism	
a. Appropriate dress and grooming	0	a. Never	0
b. Decreased interest over dressing	1	b. Occasional	1
c. Dress well if convinced by others	2	c. Sometimes	2
d. Lack of interest over dressing	3	d. Frequently	3
e. Complete aversion towards the external appearance	4	e. Constantly	4
10. SwapnaViparyaya			
Intensity of abnormal sleep disturbances		Frequency of abnormal sleep disturbances	
a. Normal sleep pattern	0	a. Never	0
b. Duration of sleep increased / decreased by 25 %, unusual dreams	1	b. Occasional	1
c. Duration of sleep increased / reduced by 50 %, less terrifying dreams	2	c. Sometimes	2
d. Duration of sleep increased / reduced by 75%, terrifying dreams	3	d. Frequently	3
e. Unable to sleep/ excessive sleep , extremely terrifying dreams	4	e. Constantly	4
11. Shaareerikalakshana			
1.Chardi	1	9.Nakhadi shouklyam	1
2.Agni saada	1	10.bhrama	1
3.Shwayathu aanane	1	11.Hridgraha	1
4.Sadana	1	12.Gaatraanaam apakarshanam	1
5.Shukla sthimithaamalopadhigdhakshatwam	1	13.Ardithakruthikaranam cha vyadhehe	1
6.Kaasa	1	14.Udarditwam	1
7.Shirasaha shoonyatha	1	15.Uchwasa adhikyam	1
8.Lala sighanakasrava	1	16.Satata lomaharsha	1

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