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AN OPEN LABELLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF BRAHMA RASAYANA IN THE MANAGEMENT OF GERIATRIC DEPRESSION W.S.R TO KAPHAJA UNMADA

¹Dr. Prashant Basnet*, ²Dr. Vijayendra Bhat G. ³Dr. Dhaneshwari HA

¹Final Year PG Scholar, Department of Kayachikitsa and Manasaroga, SDM College of Ayurveda, Udupi

²Associate Professor, Department of Kayachikitsa and Manasaroga, SDM College of Ayurveda, Udupi

³Assistant Professor, Department of Kayachikitsa and Manasaroga, SDM College of Ayurveda, Udupi

*Corresponding author's Email ID: pacificbasnet18@gmail.com

ABSTRACT

Proportion of elderly population around the world is on rise. Indian context is no different and estimated prevalence of Geriatric Depression (GD) in India was found to be high as 34.4 % in a meta-analysis published in 2019. It's a huge burden upon the health system to manage this proportion of mental health disorders in elderly. In Ayurveda, Major Depressive Disorder (MDD) can be reciprocated to *Kaphaja Unmada* (KU). KU is manifested as the *astavibhrama* (confusion of eight faculties) of *manas* (psyche) namely; *mana* (mind), *buddhi* (intelligence), *smriti* (memory) etc. Depression is a sustained state of low mood and affect, anhedonia and causes the impact in person's personal life, profession and social interactions. Moreover, GD presents as a proper psychosomatic disease after diminution of physical vigour and mental acuity added upon other life crises. So, a clinical study was carried out to evaluate the effect of *Brahma Rasayana* (BR) in managing the sign and symptoms of GD using Geriatric Depression Scale (GDS) along with its effect on quality of life using WHO Quality of Life Brief Scale (WHOQOL-BREF). On observation, percentage of remission in GDS was 28.57% and improvements in other domains of WHOQOL-BREF Scale were Psychological Domain (66.53%), Social Relationships (67.67%) and Environment (33.49%). All results were statistically significant P value (= or <0.001). Thus, BR is an ideal mind-body rejuvenator for a psychosomatic condition like GD.

KEYWORDS: *Kaphaja unmada*; Geriatric Depression; *Brahma Rasayana*

INTRODUCTION

Elderly person is the one whose age has crossed 60 years. Along with the increase in life expectancy, geriatric population all over the world is on rise. India has been having more than 7% of its population as a geriatric population since the start of this millennium thus referred as a “Greying Nation”. In 2017, it was reported to have reached 9.4 %. It is steadily increasing and prediction is being made that India will be home for 300 million elderlies by 2050 and it will make 19% of the total population.^{1,2} At old age, people start experiencing not only physical morbidities like degenerative joint disease, diabetes mellitus etc., but also mental acuity also starts compromising like memory, executive functions etc. This causes the limitations for elderlies to participate in social activities. Thus, three important aspect of health physical, mental and social are in jeopardy at old age. Mental infirmities are very common in geriatric population, geriatric depression being the most common. In Indian context, breakdown of family support systems, social isolation and decrease in economic independence are also equally important causative factors of GD.³ GD has its own diagnostic and management challenges like older adults who are depressed may not all report of being sad. Likewise, they may attribute their symptoms to physical causes or stressful life events. Depressed patients may not participate in physical, speech and occupational therapy.⁴ Due to the decreased hepatic blood clearance and enzyme activity in elderly patients, side effects of psychiatric medications are seen more in elderlies like orthostatic hypotension, cardiac toxicity and conduction abnormality, sedation etc. are seen in elderlies.⁵

The pathology and symptomatology of *kaphaja unmada* resembles major depressive disorder. Perversion of eight functional faculties of mental framework of an individual characterizes *unmada*, which are namely; *mana* (mind), *buddhi* (intellect), *samijnajnana* (consciousness), *smriti* (memory), *bhakti* (devotion), *sheela* (character) and *achara* (behavior).⁶ When these perversions are associated with the vitiation of *kapha* and *tamas dosha* then *kaphaja unmada* is manifested. Its characteristic features are *tushnibhava* (depressed look), *mandvakcheshta* (slowness in activities and speech), *anaannabhilasha* (disinclination for food).⁷ Depression in a geriatric patient is considered as GD. Depression is a pervasive low mood state with anhedonia. It affects a person's thoughts, behavior and most importantly the sense of wellbeing. Depressed

person has a typical distorted cognitive triad of worthlessness like I am worthless, people and surrounding are not helpful and it is not going to improve in future.⁸

Due to increased side effects, adverse events, and drug-drug interactions of antidepressants in elderly, lack of mind-body holistic and economic approaches, this study was planned in *rasayana-shamana* line of management with *avaleha* (paste form) formulation '*Brahma Rasayana*' mentioned in *Abhayaamalakipada of Charaka Samhita Chikitsasthana*.

MATERIALS AND METHODS

Study design and sampling:

Twenty patients diagnosed as *kaphaja unmada*/Geriatric Depression aged between 60-80 years irrespective of their gender, caste and creed were selected from OPD and IPD of SDM Ayurveda Hospital, Udupi. 20 patients were registered to the study. Study was interventional, open labeled, having single group with pre and post-test design. Patients were selected purposively. Follow up of the patients were planned twice for assessment first after the completion of medicine course and second was after 1 month of completion of the medicine course.

Criteria for diagnosis:

The diagnosis was made on the basis of signs and symptoms of *kaphajaunmada*; *tushnibhava*, *mandavakcheshta*, *rahaskamata* (wanting secrecy), *sthanamekadeshe* (confining oneself to one area), *bibhatsatvam* (nauseating), *shauchadwesha* (aversion for cleanliness) etc. and criteria for depressive disorder in DSM V TR.⁹

Inclusion Criteria:

1. Patients fulfilling the diagnostic criteria
2. Patients with age group of 60-80 years of either sex.
3. Patients signed for informed consent.

Exclusion Criteria:

1. Patients of other types of *nijaunmada*, *bhutonmada*, other psychiatric illnesses and depression due to substance abuse, other organic causes.
2. Patients with severe grade depression.

3. Patients suffering from major systemic illness necessitating long-term drug treatment.

Intervention:

Patients were orally treated with *Brahma Rasayana* 12 gm minimum one hour before food (7am and 7pm) BD with warm milk as *anupana* and was continued for 28 days.

Ingredients of the drug:

The ingredients are mainly *panchapanchamula* (roots of 25 plants) for *kwatha dravya* (decoction material), *haritaki* (*Terminalia chebula*) and *amalaki* (*Phyllanthus emblica*) as *pishthidraavyas* (powder material) and as *prakshepa dravyas* (dry fine powder) comprises 15 drugs out of which few drugs are having *medhya* (intellect enhancer) property; *shankhapushpi* (*Convolvulus pluricaulis*), *vacha* (*Acorus calamus*), *mandukaparni* (*Centella asiatica*), *yesthimadhu* (*Glycyrrhiza galbra*) like *medhya* drug are used.¹⁰ Drug was procured from SDM Ayurveda Pharmacy, Udupi.

Assessment:

Assessment was done using Geriatric Depression Scale (GDS)¹¹, Kaphaja Unmada Validated Scale (KUVS), Manasabhava Rating Scale and WHO Quality of Life Brief Scale (WHOQOL-BREF)¹² before treatment i.e., 0th, after treatment i.e., 28th and on 56th day for follow up. Statistical analysis of the results was done by Wilcoxon signed rank test using the scoring of parameters done on day 0 and 28th day.

OBSERVATION AND RESULTS

The observation made on the 20 patients showed that majority of patients i.e., 65% of the patients belonged to age group of 60-64 years, 85 % patients were females, 80 % of the patients belonged to Hindu Religion and 65.0% were married. Regarding the educational status maximum of patients i.e., 35 % were uneducated. These all observations are congruent to the characteristic features of population nearby the hospital area. More females are shown even in general population to have more depression rates than males. Majority of the patient belonged to middle-class i.e., 70%, while home-makers made 70 % of the sample, 80 % had the gradual onset of the symptoms and 55 % had the continuous course of disease. About the severity of the

disease, 55% reported mild severity of the symptoms and maximum of patients i.e., 40% had duration of disease >2 months to <12months. (Table No. 1)

Table No. 1: Distribution of Patients According to Majority of Observations (n=20)

Observations	No of Patients	Percentage (%)
AGE GROUP (60-64 years)	13	65
FEMALES	17	85
HINDU	16	80
MARRIED	13	65
UNEDUCATED	7	35
SOCIOECONOMIC STATUS-MIDDLE CLASS	14	70
HOME MAKERS	14	70
GRADUAL ONSET	16	80
CONTINUOUS COURSE	11	55
MILD SEVERITY	11	55
>2 MONTHS TO <12MONTHS DURATION	8	40

The analysis of the data obtained after the completion of medicine course revealed that percentage of remission obtained in GDS was 28.57% and that in kaphaja unmada Validated Scale was 22.40%. Regarding the effect of intervention on *manasabhavas* (emotions of mind), 30.51% reduction in intensity of Negative *Manasabhavas* was achieved after treatment, while concurrently 40.73%improvement in Positive *Manasabhavas* was achieved. Improvement in physical health domain of WHOQOL-BREF was 34.73%, improvement in other domains of WHOQOL-BREF Scale were Psychological Domain (66.53%), Social Relationships (67.67%) and Environment (33.49%). All results were statistically significant P value (= or <0.001). The analyses of the data obtained on follow up revealed that the effect of intervention on different parameters of assessment were still sustained and improving too. (Table No. 2-9)

Table No. 2: EFFECT OF TREATMENT ON SCORE OF GDS-SF

GRO UP n=20	BT Mean	AT Mean	Diff D BT- AT	% OF Relief	Wilcoxon's Signed rank test				
					SD	SEM	MEDIA N	Z VALUE	P VALUE
					BT:1.41 0	BT:0.31 5	BT:9.00 0	-3.961	<0.001
					AT:1.74 3	AT:0.39 0	AT:6.00 0		

Table No. 3: EFFECT OF TREATMENT ON SCORE OF KUVS

GRO UP n=20	BT Mean	AT Mean	Diff D BT- AT	% OF Relief	Wilcoxon's Signed rank test				
					SD	SEM	MEDIA N	Z VALUE	P VALUE
					BT:2.09 0	BT:0.4 67	BT:12.0 00	-3.896	<0.001
					AT:2.47 3	AT:0.5 53	AT:9.50 0		

Table No. 4: EFFECT OF TREATMENT ON INTENSITY OF NEGATIVE MANASABHAVAS

GROUP n=20	BT Mea n	AT Mea n	Diff D BT- AT	% OF Relief	Wilcoxon's Signed rank test				
					SD	SEM	MEDIAN	Z VALUE	P VALUE
					BT: 1.631	BT:0.17 9	BT:0.365	-3.953	<0.001
	10.65 0	7.400	3.25	30.51 %	AT: 1.536	AT:0.13 5	AT: 0.343		

Table No.5.:EFFECT OF TREATMENT ON INTENSITY OF POSITIVE MANASABHAVAS

GROUP n=20	BT Mean	AT Mean	Diff D BT- AT	% OF Relief	Wilcoxon's Signed rank test				
					SD	SEM	MEDIAN	Z VALUE	P VALUE
					BT: 3.031	BT:0.6 78	BT: 18.500	3.937	<0.001
	19.15 0	26.95 0	7.8	40.73 %	AT: 3.486	AT:0.7 80	AT: 25.00		

Table No. 6: EFFECT OF TREATMENT ON QUALITY OF PHYSICAL HEALTH

GROUP n=20	BT Mean	AT Mean	Diff D BT- AT	% OF Relief	Wilcoxon's Signed rank test				
					SD	SEM	MEDIAN	Z VALUE	P VALUE
					BT: 7.089	BT:1.5 85	BT:25.00 0	2.990	=0.001
	22.60 0	30.45 0	7.85	34.73	AT: 8.488	AT: 1.898	AT:31.00 0		

**Table No. 7:EFFECT OF TREATMENT ON QUALITY OF PSYCHOLOGICAL DOMAIN-
WHOQOL-BREF**

GROU P n=20	BT Mean	AT Mean	Diff D BT- AT	% OF Relief	Wilcoxon's Signed rank test				
					SD	SEM	MEDIA N	Z VALUE	P VALU E
					BT: 14.73 7	BT: 3.295	BT:22.0 0	3.638	<0.00 1
	25.70 0	42.80 0	17.10 0	66.53	AT: 12.72 2	AT: 2.845	AT:44.0 0		

Table No. 8: EFFECT OF TREATMENT ON QUALITY OF SOCIAL RELATIONSHIPS-WHOQOL-BREF

GROU P n=20	BT Mea n	AT Mea n	Diff D BT- AT	% OF Relief	Wilcoxon's Signed rank test				
					SD	SEM	MEDIA N	Z VALU E	P VALU E
					BT: 12.80 2	BT: 2.863	BT: 22.000	3.844	<0.001
					AT: 13.31 2	AT: 2.977	AT: 37.500		

Table No. 9: EFFECT OF TREATMENT ON QUALITY OF ENVIRONMENT

GROU P n=20	BT Mea n	AT Mea n	Diff D BT- AT	% OF Relief	Wilcoxon's Signed rank test				
					SD	SEM	MEDIAN	Z VALUE	P VALUE
					BT: 14.56 5	BT: 3.257	BT: 28.000	3.834	<0.001
					AT: 14.73 0	AT:3. 294	AT: 38.000		

Overall effect of therapy:

On analyzing all the data recorded before and after the treatment, majority of the patients 70% had shown average remission of symptoms, 5% of patients had shown moderate remission. 25% of patients had shown poor remission and none had shown worsening of the symptoms. (Figure No. 1)

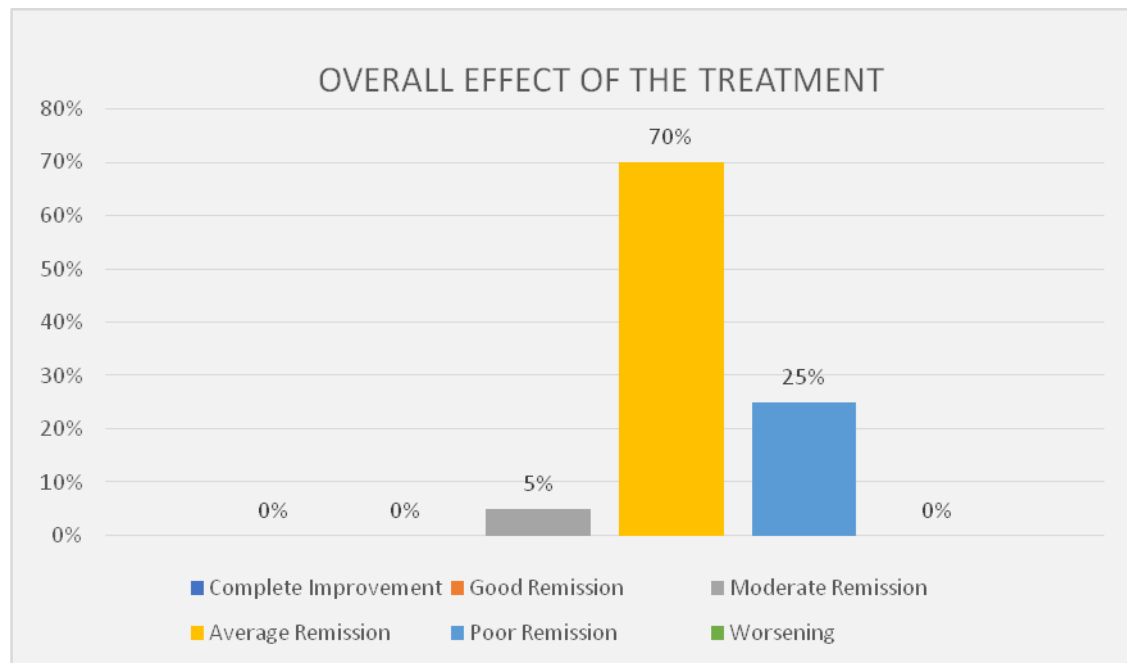


Figure No. 1: Overall Effect in Percentage

Note-

Complete Improvement	-100% Improvement
Good Remission	- Improvement from 76-99.99%
Moderate Remission	- Improvement from 51-75.99%
Average Remission	- Improvement from 26-50.99%
Poor Remission	- Improvement from 1-25.99%
Worsening	- Worsening

DISCUSSION

Geriatric Depression is a body-mind disease, which has been inadequately diagnosed and treated around the world; even lower in the developing countries like India. *Sampurana* (over nourishment) and *mandacheshta* (sedentary habits) are the two clinically objective etiological factors of KU that can be marked out.¹³ But especially in the case of the GD, the factors like the progressive loss of bulk and function of body

tissues like *mamsa* (muscle tissue), *asthi* (bone tissue), *snayu* (nerve tissue) and mind with increasing age is noteworthy in the process of causation and exacerbation of the condition.¹⁴ The better clinical outcome can be expected if the intervention is initiated in the earlier stages of disease process when prodromal symptoms like *shira sunyata* (feeling of emptiness in head), *unmatta chittam* (fickle mindedness), *udwega asthane* (anxiety at improper place) are noted.¹⁵ *Jara* (geriatric) aspect of GD is non-modifiable risk factor as it is *swabhava vyadhi*, meaning that it culminates naturally after certain time but still its effect on body and mind can be minimized by administering *rasayana chikitsa* (rejuvenation therapy).¹⁶ *Brahma Rasayana* is one unique formulation among *rasayana* (rejuvenation drug) due to the fact that it is fortified with adequate number of *medhya dravyas* to make it efficacious for the patients of GD as well.

This formulation contains multiple drugs like distinguished drug like *amalaki* for the rejuvenation and antioxidant action. While, *medhya* ingredients like *shankhapushpi*, *vacha*, *mandukaparni* acts to keep mind alert, contented mood and efficient cognition. *Panchapanchamula* pacifies associated *vata* features (related to *dosha* responsible for movement and cognition) of old age. Most of the drugs are having the *kashaya* (astringent), *katu* (pungent), *tikta* (bitter) *rasa* (taste) predominance and *tridosahara* (pacifying all three dosas), *kaphavatashamaka* (pacifying mainly *vata* and *kapha*) property. *Amalaki*, *ghrita* (ghee) are *jeevaniya ganadravyas* (vitalizing drugs) helps in balancing *ushna-tikshna* (hot and sharp) property to give *balya* (strengthening) effect to the geriatric depressed patients. The selected formulation has the desired property to act on Geriatric Depression/ *Kaphaja unmada*. *Ghrita*, *madhu* (honey) and *tila taila* (sesame oil) further increases the efficacy of the active chemical constituents by increasing their bioavailability.¹⁷

Due to all above reasons, drug caused average and moderate remission 70% and 5% of patients respectively though the intervention was instituted for only a single month. None of the patients showed worsening of the symptoms. This result proves the therapeutic efficacy of *Brahma Rasayana* in the management of Geriatric Depression/ *kaphaja unmada*.

As the proper diagnosis still remains difficult in the primary care center in the rural areas where most of the older population resides, available health care manpower

should be trained adequately to note the usually masked important signs of GD like depressed mood or to differentiate co morbid cognitive deficits. Indian culture has always seen elders as the torchbearers, source of knowledge and wisdom for the society. But due to recent breakdown in family systems in India, elder lies have felt downgraded in their own families and society. Every care should be taken to make them feel cared and understood. This is the need of the hour to assimilate the resources in the direction of screening, diagnosing and managing the maximum number of GD cases in a country like India where prevalence rate is high as 34%.¹⁸ Intervention which is economical, palatable and with minimum side effect and adverse reaction profile should be chosen. Brahma Rasayana can be one such drug with most of those qualities.

CONCLUSION

The unique features of the GD should always be considered to successfully manage the condition. Those features are mainly the reduced cognitive abilities, physical strength and reduced or misleading expression of the pertaining features. So, *Brahma Rasayana* acted to improve the cognition as well as the physical strength. Thus, remission in all the sign and symptoms of GD was achieved. The quality of life being directly related to the mental health, also improved in all four domains. But this study was limited to only 20 participants due to the time limitation of post graduate study. Further study is suggested in multicentric format with larger sample size considering the *prakriti* (natural somatic and mental constitution), *satva* (tolerance capacity of mind), *satmya* (habituation) like *dashavidha pariksha* (tenfold examination) of patients to further strengthen and generalize the findings of this study.

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