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An Open Labeled Clinical Study to Evaluate the Efficacy of *Unmadagajankusha Rasa* and *Shastika Shali Pinda Sweda* in Post Stroke Depression w.s.r to *Margavaranajanya Unmada*

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ABSTRACT

An open labeled clinical study to evaluate the efficacy of *unmadagajankusha rasa* and *shastika shalipinda sweda* in post stroke depression w.s.r to *margavaranajanyaunmada* **Objective:** To evaluate the efficacy of *Unmadagajankusha rasa* and *Shastika Shalipinda Sweda* in Post Stroke Depression/*Margavaranajanya Unmada*. **Methodology:** An open labelled clinical study with pre and post-test design. 20 patients diagnosed as post stroke depression were selected from Shri Dharmasthala Manjunatheshwara Hospital of Ayurveda, Udupi, Karnataka were subjected with *Shastika shali Pinda Sweda* for 7 days and *Unmadagajankusha Rasa* in 250mg BD with *usna jala* for a period of 28 days. Outcome was assessed before and after intervention using NIH stroke scale and Hamilton's rate of depression scale which were primary outcome measures, and secondary outcome measures were *manasikabhava pariksha* scale, *manasika bhava* scale which includes positive and negative emotions. All the parameters were statistically analysed with Wilcoxon signed rank test. **Result:** Statistically significant results were found in all parameters with p value <0.001. **Conclusion:** *Shastika Shali Pinda Sweda* and *Unmada Gajaankusha Rasa* a herbo-mineral formulation is effective in reducing the depressive features and in functional loss of the body. The efficacy of the medication has been proved with the statistical analysis of the parameters.

KEYWORDS

Margavaranajanya Unmada, Post Stroke Depression, *Shastika shalipinda sweda*, *Unmada Gajaankusha Rasa*.



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INTRODUCTION

Depression is one such grave disease witnessed in most of the populace. In India 4.5% of total population is suffering from depressive disorder which is characterized by helplessness, worthlessness and hopelessness. Depression starts to precipitate due to biological, genetic, and psychological factors.

Unmada is a disease of mind in which perverted mind is the main feature and it is due to either *manasikadosha* or *shareerikadosha*. Therefore *Unmada* is mentioned as the illness characterized by the perversion of *mana*, *buddhi*, *sanjna*, *smruti*, *bhakti*, *sheela*, *chesta* and *achara*, which are also known as *Astha vibhrama*.¹ *Margavarana* and *Dhatukshaya* are the major etiological factors of *Vatavyadhi*. The unique pathology in the sequel of *margavarana* is due to accumulation of *kapha* and *medas* within *raktamarga*. *Pakshagata* is a consequence of *margavarana* involving *shiomarma*.²

Stroke is a major public health problem,³ which often leads to marked physical impairment. The prevalence of disability among stroke survivors is between 24-54%.⁴ The progressive decrease in stroke mortality observed in the last few decades, and the subsequent increase of survivors with residual impairments and disabilities,

have been accompanied by a growing interest in the factors that could interfere with functional outcome and quality of life.⁵ Depression is considered as the strongest predictor of poor quality of life among stroke survivors.⁶ It is the most probable frequent emotional disorder that occurs after stroke. Numerous studies have reported that frequencies of major depression ranges from 10% to 25% and minor depression ranges from 10% to 40%.⁷ Some form of depression is considered to occur in at least one-quarter of patients in the first year after acute stroke, with the period of greatest risk being the first few months after onset. Moreover, this condition can have an adverse effect on cognitive function, functional recovery and survival.⁸

Depression which occurs after stroke cannot be ascribed to any other mental illness. Post stroke depression is frequently described as a feeling of hopelessness that interferes with quality of life. If not treated and managed appropriately post stroke depression can slow down the recovery of the organic pathology⁹. Post stroke depression comes under section of organic mental disorder. Post stroke depression is termed applied as depression which is manifested after stroke, mainly affecting the cognitive functions.



Pakshaghata manifests as a sequel of *margavarana* by *kapha* and *medas* to other morbid *dosha* and *dushya* due to specific *nidana*. In patients who are afflicted by predisposing factors of *margavarana*, further progresses when there is an involvement of *Shiromarma*,¹⁰ which mainly influences the cognitive dysfunction and depression which is more predominantly seen in almost all the patients. Hence the same is described as *Margavaranajanya Unmada* which is most likely parallel to Post Stroke Depression.¹¹ In context of *samanya chikitsa* of *Unmada*, literature specifies ‘*avrutamargena*’ which gives the meaning that *Unmada* is caused due to *avarana*.¹² In classics various treatment principles have been mentioned regarding psychological disorders, some of those are classified into *shodana*, *shamana*, *rasayana* and *bruhmana* line of treatment as *abhyantara chikitsa* and *alepa*, *swedana*, *pariseka*, *snehana*, *udvartana*, and *abhyanga* modality of treatment as *bahyachikitsa*, Meanwhile *shamana* and *rasayana* along with *bahirparimarjana chikitsa* plays an vital role in planning the treatment that mainly aimed for *vyadhipratyanika* and *sampraptivighatana chikitsa*. In this study the *Shastika Shalipinda Sweda*¹³ and *Unmadagajankusha rasa*¹⁴ are chosen. *Unmadagajankusha rasa* is one

such formulation which is especially indicated in *unmada rogaadhikara*. *Shastikashalipindasweda* is considered highly beneficial in disorders of morbid *vata* and *rakta*. This is an easy and effective procedure of *swedana* and is ideal in illnesses due to morbid *vata dosha* and also in healthy persons

METHODOLOGY

OBJECTIVES

- To evaluate the efficacy of *Unmadagajankusha Rasa* and *Shastika Shalipinda Sweda* in Post Stroke Depression /*Margavaranajanya Unmada*

MATERIALS AND METHODS

Ethical Committee Approval No. SDMCAU/ACA-49/ECA80/16-17

Design

- Study Type :Interventional
- Allocation :Non randomized
- Endpoint Classification : Efficacy study
- Intervention Model : Single group
- Primary Purpose :Treatment
- Masking :Open Label, pre-test and post-test design

Setting: Shri Dharmasthala Manjunatheshara Ayurveda hospital, Kuthpady, Udupi.

Participants: From July 2018 to January 2018, 20 patients with a definite diagnosis



fulfilling the diagnostic and inclusion criteria of Post Stroke Depression / *Margavarajanya Unmada* were selected for the study, irrespective of sex, caste and religion.

Diagnostic criteria

DSM 5-TR categorises PSD as a depressive disorder due to another medical condition (stroke in this case). It can be

A. A prominent and persistent period of depressed mood or markedly diminished interest or pleasure in all, or almost all, activities that predominates in the clinical picture.

B. There is evidence from the history, physical examination, or laboratory findings that the disturbance is the direct physiological consequence of another medical condition.

C. The disturbance is not better explained by another mental disorder (e.g., adjustment disorder with depressed mood, in which the stressor is a serious medical condition)

D. The disturbance does not occur exclusively during the course of a delirium.

E. The disturbances cause clinically significant distress or impairment in social, occupational or other important areas of functioning

Inclusion criteria

1. Patient fulfilling the DSM-V-TR diagnostic criteria [for mood disorder due

to general medical condition (stroke) with depressive features]

2. Patients between the age group 30-70 years, irrespective of race, religion and sex.

3. Patients with minimum period of 2weeks duration of an episode of stroke.

Exclusion criteria

1. Patients with family history Psychiatric illness or previous mental disorders.

2. Associated with congenital heart disease.

3. Unconscious & coma patients.

4. Intracranial infections such as Meningitis.

5. Space occupying lesions of brain such as tumors.

6. Congenital defects – diffuse sclerosis, cerebral agenesis, & other major illness.

7. Aphasic patients with least communication.

8. Those exposed to other major life events promoting depression other than the impact of stroke.

9. Those not willing for a written consent

Assessment criteria

Assessment was done on the basis of change in numerical rating scale of subjective parameters on 0th, 28th and 56th day with assessment 0 as baseline. Statistical analysis of the results was done by using Wilcoxon signed rank test for the parameters using the scores of day 0th and 28th day.



Primary outcome measures

1. Hamilton rate of depression scale¹⁵
2. National institute of health stroke scale¹⁶

Secondary outcome measures

1. Positive emotions in *Manasikabhava* scale.
2. Negative emotions in *Manasikabhava* scale.
3. Rating scale for *Manasikabhavapariksha*.
4. Katz Index of Independence in Activities of Daily Living¹⁷

Intervention

1. *Shastika Shalipinda Sweda*:

Purvakarma: *Abhyanga* with *Mahanarayana Taila* for 15 min

followed by *Shastika Shalipinda Sweda*

Duration: 7 days

2. Tab Unmadagajankusha *Rasa* orally – 250mg B.D with *ushnajala anupana*

Duration: 28 days

Follow Up

28 days after treatment

Total duration of study

56 days

Investigations included in the study is as follows

- Routine Blood investigation (Hb%, TC,DC,ESR, RBS)
- Fasting Lipid profile

- Urine routine
- ECG
- CT/MRI if required

RESULTS

Results of the treatment were assessed in terms of primary and secondary measures before and after treatment and results were analysed statistically using Wilcoxon signed rank test and the p value was obtained.

Hamilton's rate of depression scale

The initial mean score of Hamilton's rate of depression scale before treatment was 24.5 that was decreased to 15.35 after the intervention thus recording an improvement of 37.34% which shows that the drug has a very good therapeutic effect on depressive features. In most of the patients symptoms which are present in Hamilton rate of depression scale were not there, like insight, paranoid symptoms, suicide, obsessive and compulsive symptoms in these symptoms grading were 0 before the intervention. It is observed that after 3 weeks of follow up in 3 patients there was a complete remission of the symptoms. (Table no. 1)

Table 1 Effect of Treatment on Hamilton depression rating scale

HAM-D	Mean		WILCOXON SIGNED RANK TEST						
	BT	AT	BT-AT	% of improvement	SD	SEM	MEDIAN	Z VALUE	P VALUE
UGR & SSPS	24.5	15.35	9.35	37.34%	BT-8.556 AT-7.073	BT-1.193 AT-1.582	BT-28.500 AT-15.000	-3.930	<0.001



National Institute of Health Stroke Scale

Severity of stroke was assessed with national institute of health stroke scale. The mean value before treatment was 9.900 and

it was reduced to 6.950 after the treatment, there was 29.79% of improvement was observed which shows the efficacy of the trail drug in the study (Table no. 2).

Table 2 Effect of Treatment on NIH stroke scale

NIHSS	Mean		WILCOXON SIGNED RANK TEST						
	BT	AT	BT-AT	% of improvement	SD	SEM	MEDIAN	Z VALU E	P VALUE
UGR & SSPS	9.900	6.950	2.95	29.79%	BT-4.241	BT-0.926	BT-10.000	-3.436	<0.001
					AT-3.500	AT-0.746	AT-7.000		

In NIH Stroke scale, criteria's like level of consciousness, visual, sensory, and best language score was observed as 0 in 75% of the patients, which says that these criteria's were not affected in 75% of the patients before the treatment. The muscle power of 35% of the patients was graded as 4, which shows that there was a mild impairment in the functional loss of the body before the intervention.

Manasikabhava scale

Manasikabhava scale includes both positive and negative emotions. In negative emotions the primary score before treatment was 10.5 and it reduced to 6.15 and shows a marked improvement of 41.42% which shows best therapeutic effect

on negative emotions in the patients. In negative emotions symptoms like *chinta*, *shoka*, *bhaya*, *dwesha*, most of the patients had a complete remission in the follow up period. Positive emotions mean score before treatment was 18.950 and it reduced to 11.40 after the treatment thus recording a significant improvement of 39.84% which shows a very good effectiveness of the drug on positive emotions of the patients. In maximum number of patients positive emotion symptoms like *dhairyam*, *dhriti*, *medha*, *smriti* were affected severely before the intervention was done and it is observed that there is significant changes in these factors after the treatment.(Table no. 3 and 4)

Table 3 Effect of Treatment on Negative Emotion Scale

NEG-E	Mean		WILCOXON SIGNED RANK TEST						
	BT	AT	BT-AT	% of improvement	SD	SEM	MEDIAN	Z VALUE	P VALUE
UGR & SSPS	10.500	6.150	4.350	41.42%	BT-3.426	BT-0.766	BT-10.000	-3.931	<0.001
					AT-2.434	AT-0.544	AT-6.000		

Table 4 Effect of Treatment on Positive Emotion Scale



POS-E	Mean		WILCOXON SIGNED RANK TEST						
	BT	AT	BT-AT	% of improvement	SD	SEM	MEDIAN	Z VALU E	P VALUE
UGR & SSPS	18.950	11.400	7.55	39.84%	BT-6.262 AT-4.751	BT-1.400 AT-1.062	BT-19.500 AT-10.500	-3.925	<0.001

Rating Scale For Manasika Bhava Pariksha.

The rating scale for *manasikabhava pariksha* includes the *pratyatmalakshanas* of *unmada* i.e. *ashtavibhramasha* assessed by their intensity and frequency. The intensity of *manavibhrama* showed marked improvement of 41.46% and frequency, it showed significant improvement of 37.38%. The Intensity of *Buddhivibhramsha* showed 36.53% improvement and frequency showed 35.48% of improvements. Similarly, in intensity of *Smritivibhrama*, 40.90% significant improvement is noticed and in frequency also it showed 40.78% major improvement. In these three *vibhramas* maximum number of patients showed marked impairment before the intervention of the trial drug. By the results obtained, parameters showed notable improvement on the efficacy of the trail drug. Three of the patients had a complete remission in these parameters after 3 weeks of a follow up period. The Intensity and frequency of *Bhakti vibhrma* showed substantial improvements of 33.33% and 38.09%, respectively. The intensity of *sheela*

vibhrama is reduced by 31.11% and the frequency of the same is reduced by 32.06%. Intensity of *chestavibhrama* is reduced by 38.46%, and marked reduction was noticed in the frequency of *chestavibhrama* by 31.85%. This indicates that the drug has worked very well in reducing these symptoms. *Samjan* and *acharavibhrama* were least affected in the study group. In the intensity of *samjnavibhrama* it showed a good improvement of 32.25% and in frequency of *samjnavibhrama* it showed a significant improvement of 43.14%. Intensity of *acharavibhrama* showed a marked improvement of 40.90% and in frequency of *acharavibhrama* also it shows a very good improvement of 37.68% which states that the drug has a very good effect on these *vibhramas*. Overall it shows that the intervention proved to be very effective in counteracting the symptoms of *ashtavibhramasha* with significant statistical results.

Katz's index of independence in activities of daily living

Improvement of 28.75% has been noticed in the Katz index of independence in



activities of daily living. The drug shows the efficacy in improving the physical

ability of the patients in doing their daily activities. (Table no.5)

Table 5 Effect of Treatment on Katz index of independence in activities of daily living scale

	Mean		WILCOXON SIGNED RANK TEST						
	BT	AT	BT-AT	% of improvement	SD	SEM	MEDIAN	Z VALUE	P VALUE
KATZ ADL	2.85	4.0	1.15	28.75%	BT-2.434	BT-0.544	BT-2.000	2.821	0.002
					AT-1.919	AT-0.429	AT-4.000		

Overall effect of the treatment

On analysing overall effect of the intervention, 15% patient had a mild improvement, moderate improvement was seen in 75% of the patients, marked improvement was present in 5% of the patients and 5 % of the patients showed an excellent improvement, whereas none of the patients observed in the category of no improvement at all. With the *Unmadagajankusha* rasa and *Shastika ShaliPinda Sweda* there is a moderate to marked improvement in the symptoms. This shows that the drug was proved to be effective in the management of Post Stroke Depression/ *Maragavaranjanya Unmada* as 100% of the patients improved. (Table 6 Figure 1).

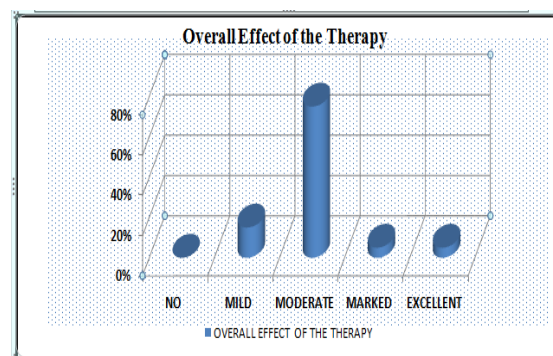


Figure 1 Overall Effect of Therapy

Table 6 Overall Effect of the Therapy

Sl. NO	IMPROVE MENT	SCA LE	NO OF PATIENTS	% OF PATIENTS
1	NO	0	0	0%
2	MILD	0-25	3	15
3	MODERATE	26-50	15	75%
4	MARKED	51-75	1	5%
5	EXCELLENT	76-100	1	5%

DISCUSSION

Swedana is the main line of treatment in *pakshaghata* which reduces *sthambha*, *gaurava*, it is indicated in *vata* and *kaphadosha*, the morbid *dosha* which are seated in *dhatu* are made *klinna* by *snehana* and gets liquefied by proper *sweda* and removes out of the body by *shodana* karma. As *pakshaghata* is one of the *vatavyadhi* due to *maragavarna* characterised by *cheshtahani*, *ruja*, *vaksthambha*, *sirasnayushosha*, *sandhibandha moksha*, were improved after the course of *shastika shalipinda sweda* which was done for 7 days after *abhyanga*. It is performed with the bolus of boiled *shali* (*Oryzasativa*), milk and decoction of *bala* (*sidacarddifolia*).



The main properties are *sukshma*, *guru*, *snigdha*, *sthira*, and *tridoshagna*. *Shashtika shalipinda sweda* has a nourishing property, which makes the body supple, removes stiffness of joints due to vitiated *vata*, cleanses the *srotas* of the body and improves blood circulation. The applications of processed rice packs are effective in emaciation, pain, stiffness, and weakness. Hence *shashtika shalipinda* is beneficial in *avarana* thus alleviates *vatadosha*.

Unmadagajankusha rasa is a *herbo mineral* formulation, which contains the main ingredients *parada*, *gandaka*, *tamra*, and *abhraka* as mineral drugs, *kanaka* (*dhattura*), *vatsanabha*, *kupilu*, and *jalapippali* are herbal drugs. *Parada* is well known for the properties like *Yogavahi*, *tridhoshgna*, *balya* *Sukshmasrotogami*, *vyavayi* etc. It is well known as *Rasayana* which with above mentioned properties nourishes all the *Rasarakta* *saptadhatus* of human body and makes it powerful and which also has its effect on *vatavyadhi*. The properties of *AbhrakaBhasma* include *prajnyabodhi*, *vrushyam*, *ayushyamagryam*, *Balyam* which underline its *Rasayana* and *medhya* properties. It generally reduces *vata* and *kapha* which in turn helps on improving cognitive impairment.

Gandaka has properties like *katu tikta rasa*, *usna virya*, *katu vipaka*, and

vatakaphagna, which also has *deepana*, *pachana*, *balya*, *yogavahi* and *rasayana* effect which helps in clearing the channels obliterated by *kapha* and *medodhatu* in *raktavahasrotas*. Thus clearing the *maragavarana*. *Tamra* which is *tiktakashaya in rasa*, *usna veerya* with the *rasyana* properties and also has its therapeutic efficacy on *vatavyadhi* which helps in correcting the *Avaranajanya Pakshaghata*.

Dhattura, *vatsanabha*, *kupilu*, *jalapippali* has properties like *ushna*, *tikshna*, *vatakaphashamaka*, which helps in correcting *avarana*. *Vatsanabha* indicated in *unmada*, which showed a beneficiary action in increasing memory and intellect. It is also a depressant that lowers neurotransmission levels, which is to depress or to reduce arousal or stimulation, which also acts as a tranquillizer. *Aconitum chasmanthum* is having a property of psycho stimulant that produces behavioural activation, usually accompanied by increased arousal, alertness and motor activity. The alkaloids found in *dhattura*, are clinically used as anticholinergic agents, which blocks the action of neurotransmitter acetylcholine at synapses in the central and the peripheral nervous system. These agents inhibit parasympathetic nerve impulses by selectively blocking the binding of the



neurotransmitter acetylcholine to its receptor in nerve cells which shows its action on extra pyramidal symptoms. *Kupilu* is CNS stimulant, that stimulates the brain, to speed up mental and physical processes. They increase energy, improve attention, alertness, improves confidence and concentration. They can increase levels of neurotransmitters in the brain such as dopamine, norepinephrine or serotonin which acts as typical and atypical antipsychotics and have clinical relevance of antidepressant.

Thus by going through the above description it shows that all the drugs of *Unmadagajaankusha Rasa* have definite action on depression as well as on motor activities and which is beneficial in post stroke depression.

CONCLUSION

As *Margavaranaunmda* is a *santarpanothavikara* due to *kapha* and *meda* in *raktamarga Unmadagajankusha* rasa is highly beneficial in *Avaranaunmada*.



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