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A CLINICAL STUDY TO EVALUATE THE THERAPEUTIC EFFECT OF SHANKAPUSHPYADI GHRITA IN THE MANAGEMENT OF KAPHAJA UNMADA W.S.R TO MAJOR DEPRESSIVE DISORDER

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ABSTRACT

Objectives: To evaluate the therapeutic efficacy of *Shankhapushpyadighrita* in patients suffering from *Kaphaja unmada* and to know the effect of *Shankhapushpyadighrita* on different mental factors. **Methods**: Interventional non-randomized open label single group study with pre-test and post-test design. Twenty patients diagnosed as *Kaphajaunmada* aged between16-70 irrespective of their gender, caste and creed were selected from OPD and IPD of SDM Ayurveda hospital, Udupi. The diagnosis was made on the basis of signs and symptoms of and depressive disorders in DSM-5 TR criteria. Patients were orally treated with S*hankhapushpyadighrita* 24ml minimum one hour before food (8am) OD with *ushnajal* (luke warm water) as *Anupana* (post prandial drink) and is continued for 28 days. Assessment was done using Hamilton's depression rating scale and *Manasika bhava* rating scale before treatment and 0^{th}, 14^{th}, 28^{th} and 56^{th} day. Statistical analysis of the results was done by Wilcoxon signed rank test using the scoring of parameters done on day 0 and 28^{th} day. **Results**: Percentage of relief in Hamilton depression scale was 28.43%, depressed mood (intensity=50%, frequency=32.35%), altered sleep (i=55.36%, f=34.56%), diminished interest(i=51.79%, f=30.83%), fatigue(i=50%, f=34.65%), changes in appetite (i=67.74%, f=39.02%), loss of confidence (i=44.11%, f=28.42%), (<0.001). *Manovibhrama* (i=43.48%f=31.85%), *Bhakthivibhrama* (i=38%, f=31.20%) *Sheelavibhrama* (i=33.96% f=33.33%), *Vachikacheshtavibhrama* (i=43.24%, f=38.05), *Shareerikacheshtavibhrama* (i=28.21%, f=32.73%), *Aacharavibhrama* (i=28.57%, f=29.41%), *Swapnaviparyaya* (i=50.91%, f=45.77%), *Shirasahashunyatha* (f=33.33%) with statistically significant P value (<0.001). **Conclusion**: All the drugs in *Shankhapushpyadighrita* possess *medhya* property. Hence it is an ideal *Shamana* medication for patients suffering from *Kaphajaunmada*/ Major depressive disorder.

Keywords: *Kaphajaunmada; Major depressive disorder; Shankhapushpyadighrita*

INTRODUCTION

Since ages, mental health has been important to human kind. *Unmada* is a disease condition presenting with *Vibhrama* of *Manas, Budhi, Samjnajnana, Smriti, Bhakti, Sheela, Cheshta* and *Achara. Kapha-*

jaUnmada is one among the 5 types of *Nijaunmada* described in the literature. *Kaphajaunmada* patient shows following features like *Tushnibhava, Anannabhilasha, Vakcheshtitamanda, Atinidra*. Depression is close equivalent to this condition.[1]

Major depressive disorder includes the symptoms like depressed mood, markedly diminished interest/ pleasure in almost all activities, significant weight loss or weight gain or decrease or increase in appetite, insomnia or hypersomnia, psychomotor agitation or retardation, fatigue or loss of energy, feelings of worthlessness or excessive or inappropriate guilt, diminished ability to think or concentrate or indecisiveness, recurrent thoughts of death, recurrent suicidal ideation or a suicide attempt. The symptoms cause clinically significant distress or impairment in social, occupational or other important areas of functioning[2].

Prevalence of depression in community samples and the prevalence rates have varied from 1.7 to 74 per thousand population. The report on Global burden of disease estimates the point prevalence of unipolar depressive episodes to be 1.9% for men and3.2% for women, and the one-year prevalence has been estimated to be 5.8% for men and 9.5% for women. It is estimated that by the year 2020 if current trends for demographic and epidemiological transition continue, the burden of depression will increase to 5.7% of the total burden of disease and it would be the second leading cause of disability-adjusted life years (DALYs), second only to ischemic heart disease.[3]

Among the different treatment measures explained for *Unmada* such as *Bahya* (fear), *Shamana* (pacificatory therapy), *Sodhanachikitsa* (purificatory measures) and *Rasayana* (rejuvenation therapy) line of management, this study is intended to identify the therapeutic measures of a *Shamana* formulation '*Shankhapushpyadighrita*' mentioned in *Unmadaadhikara* (context of *unmada*).

Consuming impure, contaminated, unwholesome, mutually contradictory food items, irregularly observing the rules for dieting are the main causes of *Unmada*. This leads to vitiation of *Tridosha* and rajas as well as tamas leads to vitiation of *Manovahasrotas* (pathway of mind), which disturbs mental emotions and produce *Unmada*. The symptoms of *Kaphajaunmada* are *Chardi* (vomiting), *Agnisada* (reduced appetite), *Sadana*(general weakness), *Aruchi* (impaired taste), *Kasa* (cough), *Alpamati* (reduced intellect), *Alpapracara, Nidraaparo* (increased sleep), *Alpakathanam, Alpabhug, Ushnasevi* (affinity towards hot regimens), *Ratraubhrusham*.[4] The therapeutic measures for the three curable types of *Unmada* are *Sneha* (oleation therapy), *Sveda* (fomentation therapy), *Vamana* (emetic therapy), *Virechana* (purgative therapy), *Asthapana* (enema therapy with Kashaya), *Anuvasana* (enema therapy with Sneha), *Upashamana, Dhooma, Dhoopana, Anjana, Avapida, Pradhamana, Abhyanga, Pradeha, Parisheka, Anulepana, Vadha, Bandhana, Avarodhana, Vitrasana, Vismapana, Vismarana, Apatarpana, Siravyadhana, Bhojanavidhanam*. [5] *Ghrita* (cow's ghee) enhances intellect, memory and plays an important role in the treatment of *Unmada*. *Ghrita* formulation, *Shankhapushpyadighrita* is described for the management of *Unmada.* It is a four-drug formulation explained in *Gadanigraha*. The ingredients are *Shankhapushpi, Vacha, Kushta* and *Brahmiswarasa.* It is indicated in *Apasmara, Unmada* and it is *Medhya*.[6]

MATERIALS AND METHODS:

Objectives of the study

- To evaluate the therapeutic efficacy of *Shankhapushpyadighrita* in patients suffering from *Kaphajaunmada.*
- To know the effect of *Shankhapushpyadighrita* on different mental factors.

Design: An interventional non-randomized single group open label clinical study with pre-test and post-test design.

Sample size: Minimum of twenty patients with a definite diagnosis of fulfilling the diagnostic, inclusion criteria of *Kaphajaunmada*/Major depressive disorder were selected for the study irrespective of sex, caste and religion.

Setting: OPD and IPD of, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Udupi.

Diagnostic criteria: The diagnosis was made on the basis of signs and symptoms of *Kaphajaunmada; Tushnibhava, Mandavak, Mandacheshta* and depressive disorders in DSM-5 TR criteria.

Inclusion criteria: Patients diagnosed as per the criteria for *Kaphajaunmada*/Major depressive disorders. No discrimination of sex, race, caste and religion and age group between 16 to 70 years old

Exclusion criteria: Patients suffering from *Nijaunmada, Bhutomada* and any other psychiatric disorders. Patients who have other organic cause responsible for depression such as hypothyroidism, fibromyalgia. Patients having substance abuse disorders.

Intervention: Oral administration of *Shankhapushpyadighrita* 24ml one hour before food (8am) OD with *Ushnajala* (luke warm water) as *Anupana.*

Duration of the study: 28 days.

Assessment criteria: Assessment was done using subjective parameters such as Hamilton's depression rating scale and *manasika* bhava rating scale on 0^{th}, 14^{th}, 28^{th} and 56^{th} day.

Statistical study: Statistical analysis of the results was done by Wilcoxon signed rank test using the scoring of parameters done on day 0 and 28^{th} day.

Observations: On observation it was found that maximum number of patients were of 31 to 40 years of age. Out of 20 patients, 40 % patients were males and 60 % were females. Most of the patients belonged to Hindu religion, were married, belongs to middle class, most of them were home-makers and were residing at *Anupadesha*, almost all had *Madhyamasara, Samhanana, Avarasatva* and *Madhyamasatmya.* Out of 20 patients included for the study 100 % patients had depressed mood, 100% patients had altered sleep, 100% of patients had diminished interest, 10 % patients had significant change in body weight, 80% patients had fatigue, 65% patients had significant changes in appetite, 70% patients had loss of confidence.

RESULTS:

Shankhapushpyadighrita showed improvement of intensity of *manovibhrama* of by 43.38%, frequency of *mano vibhrama* by 31.85%, intensity of buddhi vibhrama by 35.71%, frequency of *buddhi vibhrama* by 46.81%, intensity of *smrithivibhrama* by 28.57%, frequency of *smrithivibhrama* by 21.05%, intensity of by 38.00%, frequency of *bakthivibhrama* by 31.20%, intensity of *Sheelavibhrama* by 33.96%, frequency of *Sheelavibhrama* by 33.33%, intensity of *Vachikacheshtavibhrama* by 43.24%, Frequency of *Vachikacheshtavibhrama* by 38.05%, Intensity of *Shareerikacheshtavibhrama* by 28.21%, Frequency of *Shareerikacheshtavibhrama* by 32.73%, Intensity of *Acharavibhrama* by 28.57%, Frequency of *Acharavibhrama* by 29.41%, Intensity of *Swapnaviparyaya* by 50.91%, Frequency of *Swapna viparyaya* by 45.77%, Frequency of *Shirasahasoonyatha* by 33.33%, Frequency of *Agnisada* by 33.33%, Frequency of *Uchwasasyaadhikyam* by 36.36%, intensity of depressed mood by 50.00%, frequency of depressed mood by 32.35%, intensity of altered sleep by 55.36%, frequency of altered sleep by 34.56%, intensity of diminished interest by 51.79%, frequency of diminished interest 30.83%, intensity of significant change in body weight by 50%, frequency of significant change in body weight by 20%, Intensity of fatigue by 50%, frequency of fatigue by 34.65%, Intensity of Significant change in Appetite by 67.74%, frequency of Significant change in Appetite by 39.02%, intensity of loss of confidence by 44.11%, frequency of loss of confidence by 28.42% and mean score of Hamilton depression scale by 28.43%.

Among all the parameters, except intensity of *Budhivibhrama*, frequency of *Budhivibhrama*, intensity of *Acharavibhrama*, frequency of *Acharavibhrama* and frequency of *Shirasahasoonyatha* all showed significant result with $p<0.001$ when analysed using the Wilcoxon signed rank test.

Table 1: Showing the statistical result

Parameters	**BT** Mean	**AT** Mean	Diff **BT-AT**	% OF **Relief**	**Wilcoxon Signed rank test**				
					SD	SEM	MEDIAN	Z VALUE	P VALUE
Intensity of manovibhrama	2.300	1.300	1.000	43.48%	BT:0.733	BT:0.164	BT:2.000	-3.944	<0.001
					AT:0.470	AT:0.105	AT:1.000		
Frequency of manovibhrama	6.750	4.600	2.15	31.85%	BT: 1.118	BT:0.250	BT: 7.000	-3.961	<0.001
					AT: 0.821	AT:0.184	AT: 4.500		
Intensity of budhivibhrama	0.700	0.450	0.650	35.71%	BT: 0.801	BT:0.179	BT:0.500	-2.236	0.063
					AT: 0.605	AT:0.135	AT: 0.000		
Frequency of budhivibhrama	2.350	1.250	1.100	46.81%	BT: 2.834	BT:0.634	BT: 0.000	-2.682	0.004
					AT: 1.832	AT:0.410	AT: 0.000		
Intensity of smrithivibhrama	0.350	0.250	0.100	28.57	BT: 1.118	BT:0.250	BT: 7.000	-3.961	<0.001
					AT: 0.821	AT:0.184	AT: 4.500		
Frequency of smrithivib-hrama	0.950	0.750	0.200	21.05	BT: 0.587	BT:0.131	BT: 3.000	-3.819	<0.001
					AT: 0.444	AT:0.099	AT: 2.000		
Frequency ofbakthivibhrama	6.250	4.300	1.950	31.20%	BT: 1.164	BT:0.260	BT: 6.000	-3.985	<0.001
					AT: 1.081	AT:0.242	AT: 4.000		
Intensity of bakthivibhrama	2.500	1.550	0.950	38.00%	BT: 0.607	BT:0.136	BT: 3.000	-3.755	<0.001
					AT: 2.049	AT:0.114	AT: 2.000		
Intensity of sheelavibhrama	2.650	1.750	1.950	33.96%	BT: 0.587	BT:0.131	BT: 3.000	-3.819	<0.001
					AT: 0.444	AT:0.099	AT: 2.000		
Frequency of sheelavibhrama	6.000	4.000	2.000	33.33%	BT: 2.200	BT:0.492	BT: 6.500	-3.758	<0.001
					AT: 1.376	AT:0.308	AT: 4.000		
Intensity of vachikacheshta-vibhrama	1.850	1.050	0.800	43.24%	BT: 0.813	BT:0.182	BT: 2.000	-3.358	<0.001
					AT: 0.510	AT:0.114	AT: 1.000		
Frequency of vachikacheshtavibhrama	5.650	3.500	2.150	38.05%	BT: 1.496	BT:0.335	BT: 6.000	-3.868	<0.001
					AT: 1.539	AT:0.344	AT: 4.000		
Intensity of sharrerikacheshtavibhrama	1.950	1.400	0.550	28.21%	BT: 0.510	BT:0.114	BT: 2.000	-3.051	<0.001
					AT: 0.503	AT:0.112	AT: 1.000		
Frequency of sharrerikacheshtavibhrama	5.500	3.700	1.800	32.73%	BT: 1.235	BT:0.276	BT: 5.000	-3.773	<0.001
					AT: 1.261	AT:0.282	AT: 4.000		
Intensity of acharavibhrama	1.050	0.750	0.300	28.57%	BT: 0.759	BT:0.170	BT: 1.000	-2.121	0.063
					AT: 0.444	AT:0.099	AT: 1.000		
Frequency of acharavib-hrama	3.400	2.400	1.000	29.41%	BT: 2.210	BT:0.494	BT: 4.000	-3.011	0.002
					AT: 1.635	AT:0.366	AT: 3.000		
Intensity ofSwapnaviparyaya	2.750	1.350	1.400	50.91%	BT: 0.444	BT:0.099	BT: 4.000	-4.053	<0.001
					AT: 0.587	AT:0.131	AT: 3.000		
Frequency of Swapnavi-paryaya	7.100	3.850	3.250	45.77%	BT: 1.774	BT:0.397	BT: 8.000	-3.981	<0.001
					AT: 1.599	AT:0.357	AT: 4.000		
Frequency of shirasaa-hasoonyatha	2.250	1.500	0.750	33.33%	BT: 2.954	BT:0.660	BT: 0.000	-2.565	0.008
					AT: 2.115	AT:0.473	AT: 0.000		
Intensity of depressed mood	2.800	1.400	1.400	50.00%	BT: 0.410	BT:0.092	BT: 3.000	-4.053	< 0.001
					AT: 0.503	AT:0.112	AT:1.000		
Frequency of depressed mood	6.800	4.600	2.200	32.35%	BT: 0.768	BT:0.172	BT: 7.000	-3.963	< 0.001
					AT: 0.754	AT:0.169	AT:5.000		
Intensity of altered sleep	2.800	1.250	1.550	55.36%	BT: 0.410	BT:0.092	BT: 3.000	-4.041	< 0.001
					AT: 0.444	AT:0.099	AT:1.000		
Frequency of altered sleep	6.800	4.450	2.35	34.56%	BT: 0.696	BT:0.156	BT: 7.000	-3.980	< 0.001
					AT: 0.686	AT:0.153	AT:4.000		
Intensity of diminished inter-	2.800	1.350	1.45	51.79%	BT: 0.410	BT:0.091	BT: 3.000	-4.041	< 0.001

est					AT: 0.489	AT:0.109	AT:1.000		
Frequency of diminished interest	6.650	4.600	2.05	30.83%	BT: 0.671	BT:0.150	BT: 7.000	-3.988	< 0.001
					AT: 0.883	AT:0.197	AT:4.500		
Intensity of fatigue	1.900	0.950	0.950	50%	BT: 1.071	BT:0.240	BT: 2.000	-3.578	< 0.001
					AT: 0.605	AT:0.135	AT:1.000		
Frequency of fatigue	5.050	3.300	1.750	34.65%	BT: 2.685	BT:0.600	BT: 6.000	-3.555	< 0.001
					AT: 1.750	AT:0.391	AT:4.000		
Intensity of appetite	1.550	0.500	1.050	67.74%	BT: 1.234	BT:0.276	BT: 6.000	-3.555	< 0.001
					AT: 0.513	AT:0.115	AT:4.000		
Frequency of appetite	4.100	2.500	1.600	39.02%	BT: 3.127	BT:0.699	BT: 6.000	-3.225	< 0.001
					AT: 2.164	AT:0.484	AT:3.500		
Intensity of loss of confidence	1.700	0.950	0.75	44.11%	BT: 1.218	BT:0.272	BT: 2.000	-3.225	< 0.001
					AT: 0.759	AT:0.170	AT:1.000		
Frequency of loss of confidence	4.750	3.400	1.35	28.42%	BT: 2.936	BT:0.656	BT: 6.000	-3.354	< 0.001
					AT: 2.137	AT:0.478	AT:4.000		
Hamilton depression scale	20.750	14.850	5.900	28.43%	BT: 2.900	BT:0.648	BT:20.500	-3.927	< 0.001
					AT: 2.277	AT:0.509	AT:15.500		

DISCUSSION

In this present study, a total of 20 patients suffering from *Kaphajaunmada*/ Major depressive disorder were registered for the study from the OPD and IPD of, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Udupi after taking signed consent. Patients were diagnosed on the basis of signs and symptoms of *Kaphajaunmada; Tushnibhava, Mandavak, Mandacheshta* and diagnostic criteria for major depressive disorders in DSM-5. Pre and post-test design was planned and patients were subjected to oral administration of Shankhupushpyadighrita 24ml one hour before breakfast with *Ushnajala* as *Anupana* for 28 days. Assessment was done using Hamilton's depression rating scale and *manasika bhava* rating scale before treatment and 0^{th}, 14^{th}, 28^{th} and 56^{th} day. Statistical analysis of the results was done using Sigma Stat Statistics software version 3.5. Wilcoxon signed rank test was used to analyse the scoring of parameters on day 0 and 28^{th} day.

Mode of action: *Shankhapushpi* is a nervine tonic, possesses anti-stress activity, anti-depressant activity by its interaction with adrenergic, dopaminergic and serotonergic systems. *Shankhapushpi* increases acetylcholine content in the hippocampus. The chemical components such as glycosides, flavonoids, anthocyanins, alkaloids, sitosterol glycoside, hydroxycinnamic acid all these metabolites contribute to its nootropic and memory enhancing properties. It can act effectively on *Kaphajaunmada* and acts for the reduction of all the symptoms. *Vacha* has sedative, anticonvulsic hypothermic effects. The chemical constituents present in *Vacha* such as α-asarone and β-asarone have tranquilising action. The acetylcholinersterase enzyme activity of *Vacha* can be ascribed to b-asarone and it improves the cognition and memory. It shows this drug can act on *Mano Vibhrama, Buddhi Vibhrama, Smrithivibhrama, Vachikacheshtavibhrama* and *Swapnaviparyaya* effectively. *Brahmi* have the chemical constituents' brahmoside and brahminoside which are responsible for CNS action. As a nervine adaptogen, constituents of it are capable of increasing intelligence and memory. Anti-fatigue property is due to the presence of chemical constituent asciaticoside. It also inhibits the memory impairment induced by scopolamine through the inhibition of acetylcholine. Hence it is clear that this drug was well acted on Major depressive disorder especially on the symptoms like memory loss, fatigue, poor concentration, psychomotor retardation. Combining the properties of *Ghrita* (cow's ghee) and drugs mentioned in Shankhapushpyadighrita, makes the formulation as a perfect intervention for *Kaphajaunmada*. Based on these facts it can be said that the Shankhapushpyadighrita with drugs like *Shankhapushpi, Mandookaparni, Vacha* and *Kushta* as ingredients is effective in mental disorders and act as a brain stimulator.

CONCLUSION

Oral medication of Shankhapushpyadighritha in a dose of 24ml OD with *Anupana* as *Ushnajala* was effective in the remission of signs and symptoms of *Kaphajaunamda*. Percentage of relief got in following subjective parameters were- Hamilton depression scale 28.43%, depressed mood (intensity=50%, frequency=32.35%), altered sleep (i=55.36%, f=34.56%), diminished interest (i=51.79, f=30.83), fatigue (i=50%, f=34.65%), changes in appetite (i=67.74, f=39.02%), loss of confidence (i=44.11%, f=28.42%), *Manovibhrama* (i=43.48%f=31.85%), *Bhakthivibhrama* (i=38%, f=31.20%) *Sheelavibhrama* (i=33.96% f=33.33%), *Vachikacheshtavibhrama* (i=43.24%,f=38.05), *Shareerikacheshtavibhrama* (i=28.21%, f=32.73%), *Acharavibhrama* (i=28.57%, f=29.41%), *Swapnaviparyaya* (i=50.91%, f=45.77%), *Shirasahashunyatha* (f=33.33%). On analysing all the data recorded before and after the treatment, majority of the patients 80% had shown average remission of symptoms, 5% of patients had shown moderate remission. 15% of patients had shown poor remission and no patients had shown worsening of the symptoms.

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