



Research Article

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EVALUATION OF THERAPEUTIC EFFECT OF VACHADI GHRITA IN PATIENTS OF MILD TO MODERATE DEPRESSION

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ABSTRACT

Depressive disorders universally affect wide population due to causative factors such as irregular food habits, peer pressures and mental stress. Traditional Ayurveda literature reveals that the pre-monitory symptoms of Unmada [Insanity] and Vishad term used in ayurvedic classics can be correlated with symptoms of depression, denoting restricted activities of speech, body and mind. In management of these disorders Ayurveda explains various medicated ghee formulations which are fore most drug of choice due to its lipophilic nature. Vachadi ghrita (VG) is one of the medicated ghee formulations, contains eight herbal drugs along with Cow ghee. In this study assessment of therapeutic effect of VG was done in mild to moderate patients of depression using Hamilton scale test (HAM-D). Study group patients received VG plus standard antidepressant drugs while patients from control group received standard antidepressants. Significant change in HAM-D scores was noted after 60 days treatment of both groups when compared with their base line scores. However, no statistical significant difference was noted in HAM-D scores of studies, drug group when compared with HAM-D scores of standard drug group. As a result, it can be said that in this exploratory study VG didn't show positive effect as adjuvant drug in treatment of mild to moderate depression. Moreover, certain encouraging effects came across with administration of study drug which showed increase in patient's appetite and bowel evacuation easily as compared to standard drug. Thus, to find affirmative effect of VG further research work should be conducted in large sample size.

Key Words: Vachadi ghrita, Vishad, Unmad, Hamilton scale test for depression [HAM-D], Mild to moderate depression.

INTRODUCTION

Depression is a mood disorder characterized by loss of interest, feelings of guilt, reduced desire of sex etc¹. Traditional ayurvedic literature reveals that changes in dietary and lifestyle habits leads to disturb the equilibrium of mental and physical attributes, results to occur mental illnesses such as Unmada [Insanity] and Apasmar [Epilepsy]²⁻³. The pre-monitory symptoms of Unmada viz emptiness in thought, dysfunction of intellect, impairment of memory and symptoms stated in Vishad such as restricted activities of speech, body and mind can be correlated with symptoms of depression.³⁻⁴

Depressive disorder affects 121 million people worldwide and hampers a person's ability to work, form relationships, and destroy their quality of life⁵. To manage these manifestations, antidepressant drugs show remarkable positive effects but have been reported for adverse anticholinergic and gastrointestinal effects such as nausea, constipation, arrhythmias, weight gain, and sexual dysfunction⁶.

Thus, it is essential to find out potential drugs from Indian alternative medicine to enhance effects and minimize specific adverse drug reactions of current treatment drugs. In Ayurveda, medicated ghee formulations are the drug of choice due to their lipophilic nature and are prescribed in management of mental illnesses. Vachadi Ghrita (VG) is one of the medicated ghee formulations indicated to improve cognitive functions. It comprises of Vacha (*Acorus calamus*), Guduchi (*Tinospora cordifolia*), Shati (*Hedychium spicatum*), Haritaki (*Terminalia*

chebula), Shankhapushpi (*Convolvulus pluricaulis*), Vidanga (*Embelia ribes*), Shunti (*Zingiber officinale*), Apamarga (*Achyranthes aspera*) and Go-ghrita (Cow ghee)⁷. In previous researches, contents of Vachadi Ghrita have showed antidepressant, antipsychotic, anti-stress antioxidant, memory enhancer, anticonvulsant activities⁸⁻¹⁴. Nootropic and antipsychotic activity of VG is also proven in Morris Water Maze ($p \leq 0.001$) and 5 HTP induced head twitches ($p \leq 0.001$) mice models respectively¹⁵. Vachadi Ghrita showed positive effect on healthy person's memory¹⁶. Thus, putting all these researches together, it is emphasised that VG might show desired effect in management of depression. Hence an exploratory clinical study was planned to assess therapeutic effect of Vachadi Ghrita in the patients of mild to moderate depression.

MATERIALS AND METHODS

Preparation of Vachadi ghrita⁷

Vachadi ghrita was prepared as per standard ayurvedic protocol. Fine powders of all herbal drugs were made into paste form by adding water, the solid mass is then added to cow ghee which was previously heated and cooled down. Mixture was stirred and then water was added as per quantity given in formula. Whole mixture was heated to evaporate total water content and to achieve extraction of active components of drugs in lipid base. VG was then filtered and stored in dry containers. Laboratory analysis of VG was done using API parameters. The evaluation of formulation is given in Table no1.

Clinical Study

Before commencement of clinical study permission from institutional human ethics committee was taken, clearance was achieved on date 19/04/2015. Study has been registered to clinical trial registry of India (CTRI) with acknowledgement number REF/2016/07/011693.

Study Design

Open label non randomized standard control clinical trial.

Subjects: Patients of mild to moderate depression from Pune region. 25-50 years age group patients irrespective of sex, religion, socio-economic and marital status and previously diagnosed as patients of mild to moderate depression were included in the study. Patients suffering from hypertension, diabetes mellitus, asthma, tuberculosis, malignancies, bipolar depression, depression with dementia, severe depression and trauma were not included in the study. Based on said criteria 12 patients were included in the study. Patients were pre informed about study drug effects and no any side effects. Written informed consent was obtained from patient and patient’s relatives before initiating actual study.

To begin with, patients were screened for eligibility and then in consultation to psychologist each patient’s HAM-D scores were obtained using Hamilton scale test. After confirmation of diagnosis, 12 patients of mild to moderate depression were non-randomly grouped in study and standard control groups.

On day zero HAM-D scores of each patient of both groups were recorded using Hamilton scale test.* (These tests are established

tests and internationally approved by American Psychological Association). General health assessment of each patient was done using ayurvedic and modern case paper specifically prepared for patients of CNS disorders. Personal diary was given to patient and asked them to fill the points narrated in dairy viz daily marking of drug consumption, dropped drug doses, any change if they observed in physical parameters and mental attributes. For standard control group, antidepressant drugs were given to six patients for continuous 60 days as per psychiatrist advice. For study group, administration of Vachadi Ghrita in 10 gm dose bid with Luke warm water was given. Antidepressant drugs were also given to them by keeping three hours gap. Thus, this group received [VG + antidepressant drugs].

Pre, mid and post treatment HAM-D scores of study and standard control group patients were recorded using Hamilton scale test in consultation to psychologists. After the treatment of sixty days, post medicine assessment was done wherein pre and post treatment HAM-D scores were compared of both groups. In addition, each group pre, mid and post treatment HAM-D scores were compared. Follow up of each patient was taken on every 15 days to observe any changes in patient’s appetite, bowel habit, urination, general condition

Statistical Analysis

Whole data of HAM-D scores of day zero, day thirty and day sixty one was organized and statistically analyzed with Friedman test for study and standard control group. To compare pre and post treatment HAM-D scores of both groups, data was further analyzed with Mann Whitney test.

RESULTS

Table 1: Organoleptic parameter and analytical values of VG

Organoleptic Parameter	VG	Parameter	Values
Shabda(Sound)	No sound after putting on fire	Ph	5
Sparsh(Touch)	Picchila(Unctuousness)	Specific Gravity	0.9547
Roopa(Color)	Harita(Dark greenish)	Free Fatty acid	0.81%
Rasa (Taste)	Tikta++ (Bitter ++)	Moisture	0.18%
Gandha(Odor)	Uragandhi(Stong aromatic)	Saponification value	295.60

Table 1 indicates that Vachadi Ghrita was dark greenish in color, bitter in taste, having strong aroma and obtained Physico- chemical values of VG comply with standard values.

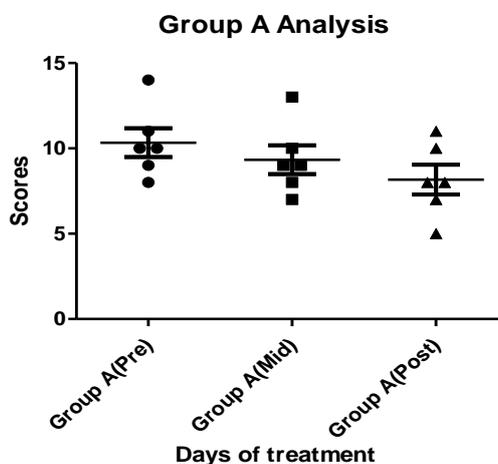


Figure 1: Comparative analysis of zero day, thirty and sixty one day HAM-D scores of study group A.
n = 6, ** P<0.01.

Significant difference was noted in HAM-D scores of study group when zero day scores compared with scores of sixty one day.

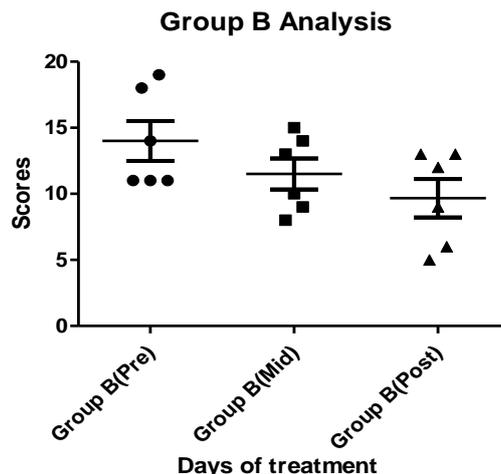


Figure 2: Comparative analysis of zero day, thirty and sixty one day HAM-D scores of standard control group B.
n = 6, ** P<0.01

For standard group gradual reduction in HAM-D score was resulted when zero day HAM-D scores were compared with sixty one day.

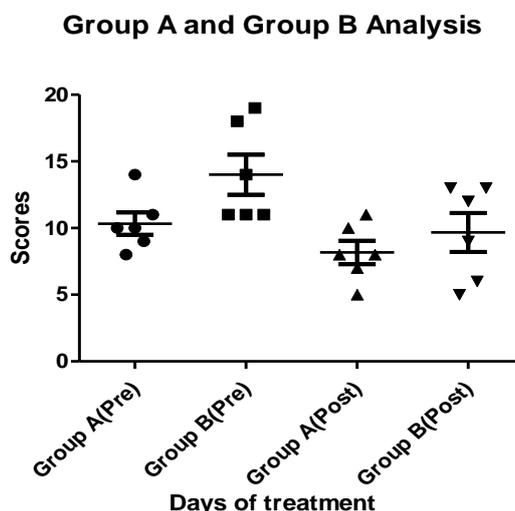


Figure 3: Comparison of HAM-D scores of study group (Group A) and standard control group (Group B)

Figure three shows before and after treatment HAM-D scores of both groups. The first set of HAM-D scores is of study group while another set of HAM-D scores are of standard control group. Significant change was not observed when pre and post treatment HAM-D scores were compared for both groups.

DISCUSSION

In this study diagnosed patients of mild to moderate depression were included in study. Patients were under standard antidepressant drugs. Vachadi Ghrita, a medicated ghee formulation, was given as adjuvant drug to patients of study drug. Data of HAM-D scores was analyzed across study drug and standard drug group.

Gradual decrease in HAM-D scores of patients of study and standard drug is seen after sixty days of treatment. Reduction in HAM-D scores implies overall improvement in both group patients. However, patients received VG along with antidepressants did not show statistical significant change in reduction of HAM-D score in comparison to patients who were on standard antidepressant drugs.

Thus, in this exploratory clinical study we could not underline the predictable effect of Vachadi Ghrita which was administered as adjuvant drug with conventional antidepressants for patients of mild to moderate depression. This might have happened due to small sample size. Second probability of getting these results can be explained in accordance to ayurvedic pharmacology of Vachadi Ghrita. The contents of Vachadi Ghrita are having therapeutic effects on improvement of intellect and memory. Maximum ingredients possess Katu[Pungent] taste, Ushna[hot] potency and Agnideepan [increases digestion ability] activity. Thus, Vachadi Ghrita as a compound formulation might be having potential to increase cognitive functions of human brain and useful to treat cognitive disorders. Earlier research works also confirmed beneficial effect of VG on healthy individual's memory. In view of that, Vachadi Ghrita would be used in patients of learning disorders and memory impairment. On the contrary in the span of sixty days treatment, study group patients showed beneficial effects as increase in appetite, easy evacuation of bowel compared to patients of standard drug. Therefore, in order to generalize the results, further studies should be carried out on larger sample size and should be investigated clinically in different cognitive disorders.

CONCLUSION

After sixty days of treatment, significant improvement in patients of mild to moderate depression was not observed for VG along with antidepressants group against standard antidepressant drug group. Thus, present study could not conclude the positive effect of Vachadi Ghrita as an adjuvant drug in the patients of mild to moderate depression.

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