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## CLINICAL STUDY OF ASSESSMENT OF THERAPEUTIC POTENTIAL OF VACHADI GHRITA, A MEDICATED GHEE FORMULATION ON HEALTHY INDIVIDUAL'S COGNITION

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**ABSTRACT:** In traditional Ayurved, numbers of medicated ghee formulations are prescribed to regulate person's cognitive functions. *Vachadi ghrita* [VG], a medicated ghee formulation is prescribed to maintain healthy process of intellect and memory. In recent experimental studies, positive action of VG on animal's memory was proved. Thus to generate clinical evidence, the study was attempted to evaluate the therapeutic potential of VG on healthy individual's memory using PGI memory scale test. **Methods:** Non randomized positive controlled clinical trial was carried out in ninety healthy individuals. Thirty participants from two groups received VG and Cow ghee respectively. Plain control group participants did not receive any drug. Drugs were administered orally in 10 gm dose twice a day for continuous 30 days. PGI memory scale was used to analyze before and after treatment effects of drugs on learning and memory ability in healthy individuals. **Results:** The participants of *Vachadi ghrita* showed significant change in scores of PGI scale as compared to the participants of plain ( $p < 0.01$ ) and cow ghee groups ( $p < 0.05$ ). Substantial change in scores of mental balance, delayed - immediate recall, retention of similar and dissimilar pairs was determined in participants of VG group compared to other two groups. Study drug [VG] showed added positive effect on participant's digestive power. **Conclusion:** *Vachadi ghrita* has significant effect on healthy individual's learning ability, verbal working and short - term memory. The present results provide an evidence for therapeutic potential of VG on healthy person's cognition.

**INTRODUCTION:** Rapid growing in human ageing is becoming a public health problem in developed and developing countries. Mild cognitive impairment (MCI) might be at risk of developing dementia, critical for targeting preventative interventions<sup>1</sup>. Demographic and clinical characteristics can predict the incident of MCI and might succeed to dementia<sup>2</sup>. The most prominent aspects of human aging present memory decline phenomenon and that intellectual capacities began to diminish<sup>3</sup>.

Thus, in the natural ageing declination in performance on daily tasks, transformation of information, taking proper decision, slow down of the process of execution and impairment of memory is observed<sup>4</sup>. In traditional Ayurvedic texts, the effect of time period on human's physical activities and on cognitive domain is well stated.

Accordingly, Medha (cognitive functions) starts to decline from the fourth decade of human's life<sup>5</sup>. To combat with health concerns in association to cognitive disorders, numbers of medicated ghee formulations are prescribed. Solid lipid nanoparticles and liposomes with certain derived peptides have been shown to facilitate cellular uptake and drug transport across a model of the BBB<sup>6</sup>. Thus it is assumed that medicated ghee formulations might be crossing BBB and produce desired target actions.

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*Vachadi ghrita* (VG) is a medicated ghee formulation, advocated to maintain cognitive abilities in normalcy (Medha and Smritivardhak) <sup>7</sup>. It comprises of eight herbal drugs along with cow ghee. In accordance to Ayurved, all contents are having specific actions towards CNS.

Moreover, in earlier studies the components of VG have been proven for their anti-depressant, anti-psychotic, anti oxidant, anti stress and nootropic activities and the potential of herbal drugs is well documented in published data <sup>8, 9, 10, 11, 12</sup>.

In experimental animal studies anti-amnesic and nootropic activities of VG were confirmed <sup>13</sup>. However, clinical investigation of VG hasn't been completed till date to explore its action on human cognition. Therefore the goal of the study was to test the therapeutic potential of VG against cow ghee and plain control in healthy individual's learning and memory using PGI memory scale.

## MATERIALS AND METHODS:

**Preparation of *Vachadi ghrita*:** It was prepared as per standard guideline stated in Ayurvedic classical text for preparation of medicated ghee formulations <sup>14</sup>. Fine powder of eight potent herbal drugs *viz.* Vacha (*Acorus calamus*), Guduchi (*Tinospora cordifolia*), Shati (*Hedychium spicatum*), Haritaki (*Terminalia chebula*), Shankhapushpi (*Convolvulus pluricaulis*), Vidanga (*Embelia ribes*), Shunti (*Zingiber officinale*) and Apamarga (*Achyranthes aspera*) were mixed homogeneously with plain water and further converted into paste form.

One part of paste was added to four parts of liquefied GoGhruta (Cow Ghee), then sixteen parts of water was added to this mixture. The whole mixture was further heated on low flame till total water content was removed and active components of herbal drugs was extracted in Cow Ghee. The resultant product was then analyzed in laboratory using API parameters.

**Clinical Trial:** This clinical trial was conducted in the out-patient clinics. It was non randomized positive controlled trial. Before commencement of the study approval from institutional ethics committee was obtained, approval number is BVDU/Exam/13-23/2014-15. This trial was registered to CTRI with Ref/2015/12/010270 number.

**Selection of Participants:** Individuals' of 40 - 50 age groups of either sex, irrespective of socio economic status, serving in secondary and higher educational campuses as teaching faculty were selected. Healthy individuals' with normal hematological values were included in the study. Participants suffering from hypertension, hypo or hyper thyroid, diabetes mellitus, asthma, obesity and other major diseases were excluded from the study. After giving complete information about the research work the consent was taken from all participants'.

On day zero, as per PGI memory scale test, participants' were asked to perform some activities *viz.* information recall, forward-backward repetition of digits, sequential formation of sentences, association of similar-dissimilar pairs, visual retention and recognition of pictures. With this method, the scores for each parameter of each participant from all three groups were recorded. General health assessment of each participant was done by using Ayurvedic case paper. A personal diary was given to participant and asked them to fill the points written in dairy *viz.* daily marking of drug consumption, dropped drug doses, any change if they observed in physical parameters and mental attributes.

**Administration of Medicine:** Ninety participants were non-randomly distributed to three groups containing thirty participants in each group. Participants of plain control group didn't receive any drug, participants of positive control group were given GoGhruta (Cow Ghee) and study group participants were given *Vachadi ghrita*. On the word of Ayurvedic principles and research works conducted on medicated oils, study drug (VG) and cow ghee were given orally in 10 gm dose twice a day with Luke warm water continuous for 30 days <sup>14, 15, 16</sup>.

**Effect of *Vachadi ghrita* and Cow Ghee on Participant's Memory:** Pre and post treatment scores of VG and cow ghee were statistically compared to assess post medicine effects on participant's learning and memory. In addition, post treatment total scores of each group were also compared. The effect of drug treatments on each parameter of PGI memory scale was also investigated and further compared.

**Effect of Vachadi ghrita and Cow Ghee on Participant's General Health:** General health examination of each participant was done by using health assessment format. On fifteenth and thirty day appetite, digestion, bowel and urination pattern of each participant was recorded.

In a similar way during drug consumption, certain symptoms such as nausea, anorexia and indigestion were also noted.

**Statistical Analysis:** Pre and post treatment total scores of study and control groups obtained from PGI memory scale test were statistically analyzed by using student paired 't' test. Post treatment scores of three groups were compared by using ANOVA followed by Tukey's test at the significance level of 95 % ( $p < 0.05$ ).

Pre and post treatment scores of each parameter of PGI memory scale of three groups were also statistically analyzed by using student paired 't' test. Qualitative data in the form of percentage was presented.

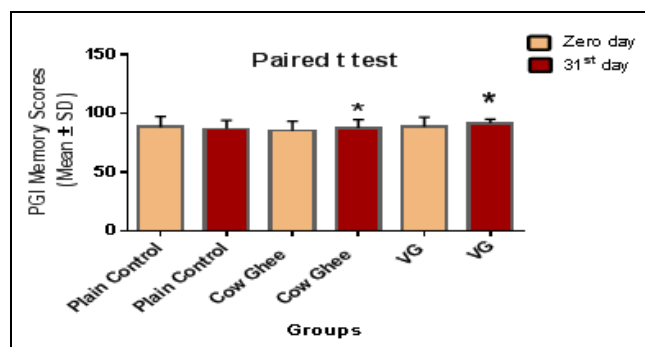


FIG. 1: BEFORE AND AFTER TREATMENT SCORES OF VACHADI GHRITA, COW GHEE AND PLAIN CONTROL GROUPS

**Effect of Vachadi ghrita and Cow Ghee on Specific Parameters of PGI Memory Scale:** Vachadi ghrita participants showed statistical significant improvement in delayed recall ( $p=0.026$ ), immediate recall ( $p=0.0006$ ) Fig. 3, 4. Moreover, VG group also demonstrated significant increase in scores of retention of dissimilar ( $p=0.043$ ) and similar pairs ( $p=0.007$ ) Fig. 5, 6. Significant change was not noted on those four parameters of cow ghee and plain control group participants.

**Effect of Drug Treatment on Other Parameters of PGI Memory Scale:** After analysis of before

**RESULTS:** Vachadi ghrita comprises of yellow colour, bitter taste, oily touch and pleasant odour. It possesses aforesaid analytical values.

TABLE 1: ORGANOLEPTIC AND PHYSICO CHEMICAL ANALYSIS OF VACHADI GHRITA

API Parameters	Vachadi ghrita
pH	5
Specific gravity	0.918
Saponification value	295.60
Acid value	1.68

**Effect of Vachadi ghrita and Cow Ghee on Participant's Memory:** After performance of PGI memory scale test, to check the effect of Vachadi ghrita against control drugs obtained scores were statistically compared. Before and after treatment scores of cow ghee ( $p=0.042$ ) and Vachadi ghrita ( $p=0.015$ ) groups showed significant change, however significant change was not determined in plain control group Fig. 1. Vachadi ghrita ( $p=0.005$ ) showed significant effect on memory scores as compared to Cow ghee ( $p=0.03$ ) and plain control groups, when post treatment scores were statistically analyzed Fig. 2.

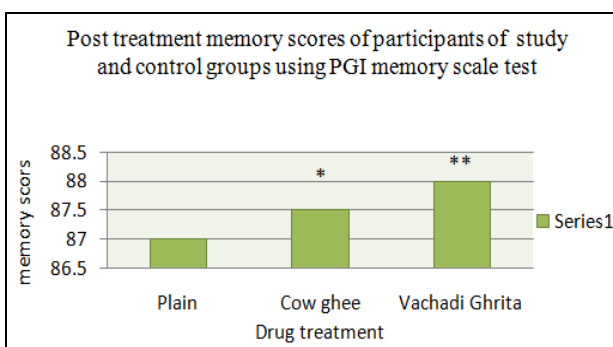


FIG. 2: POST TREATMENT MEMORY SCORES OF STUDY AND CONTROL GROUPS  
n=30, \* $p < 0.05$ , \*\* $p < 0.01$

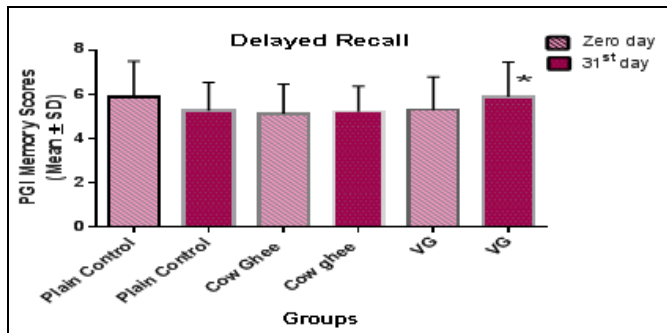
and after treatment scores of recent memory, remote memory, attention and concentration, visual retention and recognition, significant effect was not observed for study as well as control drugs.

**Effect of Drug Treatment on Participant's Appetite:** Sixty percent participants of Vachadi ghrita group showed improvement in appetite, while seventeen percent have shown decrease and twenty-three percent participants did not show any change in their appetite pattern.

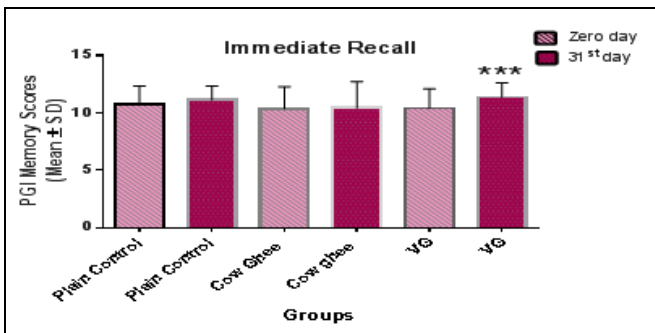
Forty percent participants of cow ghee group have shown increase in appetite while forty-three percent

participants have not shown any change in their appetite pattern. Seventeen percent participants of the same group showed reduction in appetite. Higher numbers of participants of plain control group (73%) have not demonstrated any change in their appetite pattern **Fig. 7**.

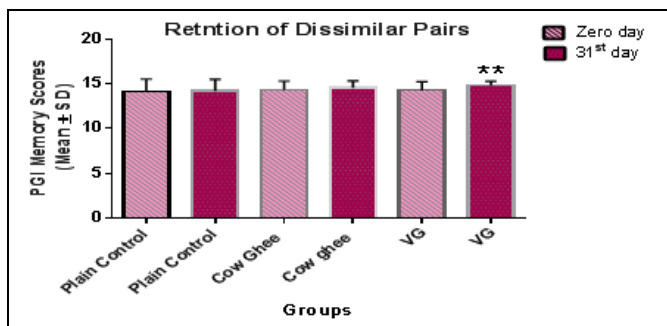
**The Effect of Treatment on Evacuation of Stools:** After thirty days of treatment 66 percent participants of VG and 46.6 percent participants of cow ghee showed easy evacuation of stools. This added positive effect was not observed for participants who did not receive any drug.



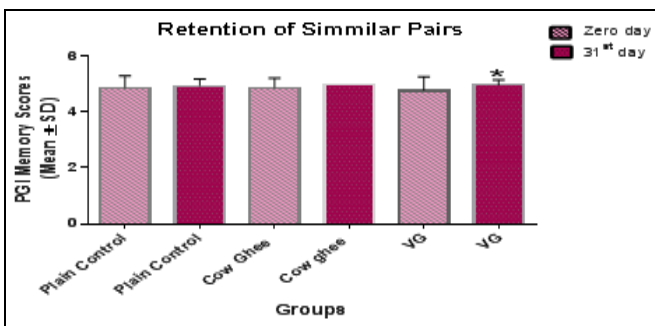
**FIG. 3: BEFORE AND AFTER TREATMENT SCORES OF DELAYED RECALL** n=30,\* p value <0.05



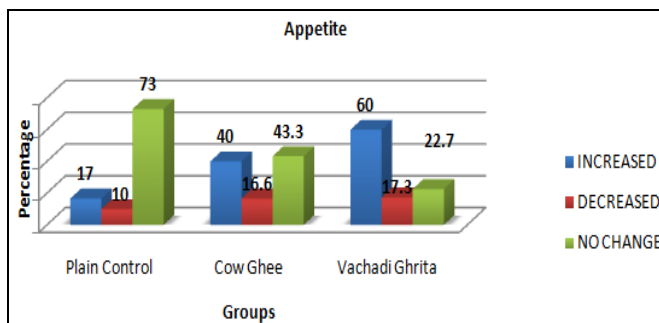
**FIG. 4: BEFORE AND AFTER TREATMENT SCORES OF IMMEDIATE RECALL** n=30, \*\*\* p< 0.001



**FIG. 5: BEFORE AND AFTER TREATMENT SCORES OF RETENTION OF DISSIMILAR PAIRS** n=30, \*\*p<0.01



**FIG. 6: BEFORE AND AFTER TREATMENT SCORES OF RETENTION OF SIMILAR PAIRS** n=30,\*p<0.05



**FIG. 7: EFFECT OF DRUG TREATMENT ON PARTICIPANT'S APPETITE**

**DISCUSSION:** In India, the symptoms of cognitive impairment are attributed to normal aging and patients usually present late course of dementia with moderate to severe cognitive deterioration, thereby delaying the interventions<sup>18</sup>. Thus, it is essential to protect elder people population against development of MCI and dementia. The preventive measures to proper treatment might improve cognitive functions in normalcy and prevent further harmful deficits. Traditional Ayurvedic repertory

has provided different medicaments to support healthy state of cognition or to treat specific cognitive disorders. *Vachadi ghrita* is one of the medicated ghee formulations advised to improve intellect and memory in human being. In present study this formulation was administered to healthy persons for thirty days. The effect of the formulation on their cognitive abilities was tested through PGI memory scale test. PGI memory scale test is a short, simple, objective and valid test for

testing of memory which is developed by the psychiatrists, neurologists and clinical psychologists working in India.

The participants enrolled in the study had not been taken any medicaments for improvement of memory as before. Adult participant's learning and memory ability, by giving correct or incorrect answers for counter factual questions relatively shown to their cognitive skills. Participants of *Vachadi ghrita* and cow ghee groups imply significant change in pre and post treatment scores ( $p < 0.05$ ). VG drug has shown significant effect ( $p < 0.01$ ) on total scores when post treatment scores were compared with cow ghee and plain control group scores. These findings of the study hence represent positive effect of VG on healthy individual's cognition.

The clarification for each parameter of PGI scale is well specified in manual; here mental balance indicates temporal sequencing with attention and concentration. Immediate and delayed recall parameters explain about person's verbal working and short-term memory. Retention for similar pairs and dissimilar pair parameters elucidate human simple and new learning ability<sup>19, 20</sup>. In this study also study drug (VG) has shown significant improvement in some of the parameters of PGI memory scale *viz* mental balance, delayed and immediate recall as well as on retention of similar and dissimilar pairs as compared to plain and cow ghee groups. Thus this result indicates that VG drug is effective to maintain or increase healthy person's concentration, sequential attention, learning ability and short term memory process.

In Ayurved, the positive actions of the contents of study drug (*Vachadi ghrita*) towards human's intellect and memory are well described. Besides, research works conducted on each contents of VG confirmed their antidepressant, antipsychotic, anti oxidant and nootropic activities in animal models<sup>8, 9, 10, 11, 12</sup>. Therefore, in accordance to Ayurved theory, synergism of said ingredients of VG might be showing antioxidant and neuroprotective activities. In this study, we found the cumulative beneficial action of VG on healthy person's learning and memory processes. Increase in appetite was the added result we found for study drug, this effect might be helpful to maintain the

healthy metabolism at cellular level and facilitate to produce cognitive enhancer activity.

Thus, along with appropriate measures (periodic monitoring of patients) and providing lifestyle guidance, *Vachadi ghrita* would be a better choice as a prophylactic agent or as an adjuvant drug in the treatment of cognitive disorders. The drug might be helpful to prevent the progressive decline of memory in elderly people. It is useful to treat mild cognitive impairment along with conventional therapy. However, further studies are to be conducted in elderly healthy persons or in the patients of MCI to explore therapeutic effect of VG as a cognitive enhancer agent.

**CONCLUSION:** The therapeutic potential of *Vachadi ghrita* as a nootropic agent is explored through this clinical study, since VG showed positive effects on improvement of cognitive functions, assessed with PGI memory scale test.

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**CONFLICT OF INTEREST:** The authors have no conflict of interests to declare about publication of this paper

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