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EVALUATION OF ANTIDEPRESSANT POTENTIAL OF AN AYURVEDIC FORMULATION PANCHGAVYA GHRITA AS AN ADJUVANT IN PATIENTS OF DEPRESSION

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ABSTRACT

Depression is a widespread psychiatric disorder affecting around 5% of the population and can be estimated to be second largest global burden of disease after heart disease by 2020. Although currently prescribed molecules for depression improve the clinical condition of patient but, it is at the worth of bearing of its adverse effects like sleep disruption, sexual dysfunction and weight gain. *PanchgavyaGhrita* is one of the frequently and consistently used formulations in Ayurvedic fraternity to treat various neuropsychological disorders. *PanchgavyaGhrita* was prepared following SOP and analytical values of PGG were matched with the established standard values. Selected pre diagnosed patients of depression were non-randomly divided into 2 groups of 6 patients in each group. Group A - Study Group- *C*onventional therapy along with *PanchgavyaGhrita*, Group B – conventional therapy. Decrease in the score of by at least 1 unit in Hamilton scale test was used as the primary outcome measure. Treatment was given for the duration of 60days. Every patient was assessed pre, mid and post treatment using Friedman test. Between groups comparison was done using Mann Whitney test. Secondary outcome measures for study by changes in certain subjective parameters. *PanchgavyaGhrita* proved as an adjuvant drug by showing antidepressant potential in the patients of depression when compared with only conventional therapy.

Keywords: *Panchagavyaghrita*, Depression, Hamilton scale test

INTRODUCTION

Depressive disorders are of outstanding socio-economic and health-economic importance as they are the psychiatric disorders that most frequently cause psychosocial disability. According to information from the World Health Organization (WHO) by virtue of the

Global Burden of Disease report 2004 they were the number one cause for moderate and severe disability independent of socio demographic factors with increasing importance in the projection to the year 2030[1]

Depression is a common mental disorder that presents with depressed mood, loss of interest or pleasure, decreased energy, feelings of guilt or low self-worth, disturbed sleep or appetite, and poor concentration.[2]It is a common illness worldwide, with an estimated 350 million people affected.[3]

AIM:

Evaluation of antidepressant potential of *PanchgavyaGhrita(PGG)* as an adjuvantin patients of depression.

OBJECTIVES:

- To manufacture *P.G.G.* following pre-established Standard Operating Procedure (SOP).
- To established standard parameters of *PanchgavyaGhrita*.
- To assess the antidepressant effect of *P.G.G.* in patients of depression of age group 25-50 years using Hamilton Depression Rating scale test.

MATERIALS AND METHODOLOGY-

DRUG DOSE: 10 gm. BD

DOSE DURATION DECISION: 60 DAY

Prior to clinical study, clearance from human ethics committee was obtained

- **Study design**- Open Labeled Non- Randomized Standard Controlled Clinical Trial.
- **Study site**-Department of RSBK, BVDUCOA & Hospital, Pune
- **Subjects**- Pre- Diagnosed patients of depression
- **Sample Size**- 12 (6 Patients in each group)

- **Inclusion criteria**-

- Pre-diagnosed patients of depressionin the age group 25-50 years of either sex.

- **Exclusion criteria:**

- Patient suffering from depressive disorder with other concomitant psychiatric disorders
- No other associated medical or surgical ailments like Hypertension, Diabetes mellitus, Asthma, Tuberculosis, Malignancies
- Pregnant women

- **DRUGS:**

- **Study Drug**: *Panchgavyaghrita (PGG)* with Conventional therapies
- **Control Drug**: Conventional therapies

PanchgavyaGhrita was manufactured in BVDUCOA, Pharmacy and values were matched with the standardized values which are pre-established.

Table 1: Grouping of patients:

Groups	Group name	Number Of patients	Drug	Drug Dose	Anupan	Duration	Time
A	Study Group (SG)	6 (Complete)	PGG with prescribed conventional therapy	10 gm BD	*Ushnajala* (hot water)	60 days	Morning and Evening On empty stomach around 6am,6pm
B	Standard Control Group (SCG)	6	Conventional therapy	As prescribed	As prescribed	As prescribed	As prescribed

Table 2: Study design: Hamilton scale test & follow-up:

	Day Zero Pre-assessment	Day-1 *PGG* starts V1 F1	Day 15- V2 F2	Day 30- V3 F3	Day 45- V4 F4	Day 60 V5 F5	Day 61 Post-assessment
Performance test- HAMILTON SCALE	✓	×	×	✓	×	×	✓
Follow-up		✓	✓	✓	✓	✓	✓

Table 3: Drug *(P.G.G.)* administration:

	Day 1 – 15	Day 16 -30	Day 31-45	Day 46-60
Drug *(P.G.G.)* administration	✓	✓	✓	✓
	Day 1 – 15	Day 16 -30	Day 31-45	Day 46-60
Drug *(P.G.G.)* administration	✓	✓	✓	✓

- **METHODOLOGY:**
- Combine case paper i.e. modern & Ayurvedic case paper was designed in Dept. of R.S.B.K.
- Diary was prepared to record daily symptoms about illness, drug consumed and symptoms related to drug consumption if any, by patient
- 19 patients fulfilled the inclusion criteria and out of these 19; seven patients refused to consume PGG for such a long duration. Thus 12 willing patients were recruited in the study
- Study was conducted in two groups with 6 patients in each group. Group A received *PanchgavyaGhrita* along with the conventional therapy & Group B was on only conventional therapy
- Patients and their relatives were informed about the purpose and the schedule of the study. A written informed consent was obtained from patient
- Assent from patient's relative was obtained

- Selected patients were non randomly allocated into 2 groups Group A and Group B each bearing 6 patients
- After grouping every patient from both groups was asked to fill the Hamilton scale test. The scores were recorded by the ratour appointed
- All six patients from study drug group patients were given *GandharvaHaritaki-Choorna* in a dose of 1 gm. Bed time with hot water for a period of 5 days
- Each patient was gave *Panchgavyaghrita* bottle measured for him/her, measuring spoon, and was shown how to take measured dose with hot water
- After 5 days of *GandharvaHaritaki* administration, on 6th day; *PGG* administration was did as per group and this is considered as the first day. Study drug duration was 60 days
- Diary was given to each patient to note down daily dose consumption and any symptoms if noticed.
- Patient was motivated not to miss the dose and suggested to use a calendar to set reminders for taking medicine in time. Every 15 days, follow up was taken and on the 30th day Hamilton scale test was used for assessment for both the groups. The scores were recorded by ratour.
- Drop out criterion: A patient who will miss a dose for 3 consecutive days i.e. 6 doses during the complete study period, will be dropped out from the project and new patient will be recruited. There was no any drop out.
- Empty bottles /unfinished bottles (to measure accuracy of dosed) was collected during the follow up.
- On day 61 each patient from both the groups was asked to take the same test (Hamilton Scale Test) again and result was recorded by ratour.
- Data was organized and analyzed by applying Friedman test and Mann Whitney test

CRITERIA FOR ASSESSMENT:

Primary Outcome Measure:

- Performance in Hamilton Scale Test

Secondary outcome measure:

- Stool
- Skin texture
- Appetite
- Sleep
- Flatulence

Method of Statistical Analysis:

Every patient was assessed pre, mid and post treatment using Friedman test.

Between groups i.e. A & B was compared using Mann Whitney test.

Results:

Table 04: Results of between group comparisons using FRIEDMAN TEST

	Median			FRIEDMAN TEST	P-Value	Result
	Pre	Mid	Post			
Group A (SG)	15	11	7	12.00	0.002	Significant
Group B (CG)	16	11	9	11.27	0.004	Significant

From above table we can observe that P-Values for both the groups are less than 0.05 thus we can claim that there is significant difference observed in both the groups.

Graph 1: Results of between group comparisons using FRIEDMAN TEST

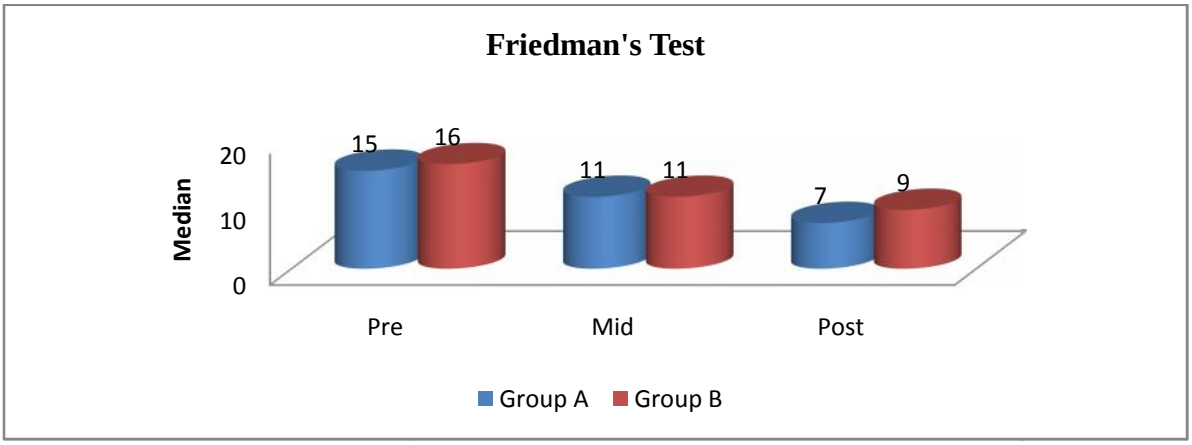


Table 05: Results of intra group comparison Day zero and day thirty:
For pair wise comparison at Day 0, Day 30 and Day 61 Wilcoxon Signed Rank testwas used.

	Median		Wilcoxon Signed Rank W	P-Value	Result
	Day 0	Day 30			
Group A (SG)	15	11	-2.214[a]	0.027	Significant
Group B (CG)	16	11	-2.232[a]	0.026	Significant

From above table we can observe that P-Values for both the groups are less than 0.05 hence we can say that there is a significant change observed in day 0 and day 30 scores for both the groups.

Graph 2: Results of intra group comparison Day zero and day thirty:

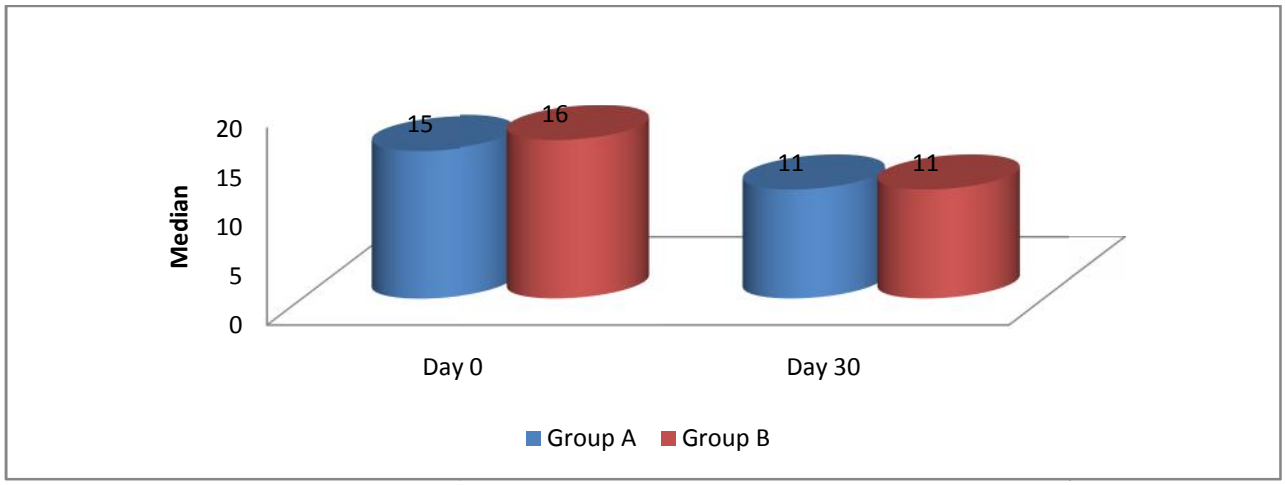


Table 06: Results of intra group comparison Day zero and day sixty one:

	Median		Wilcoxon Signed Rank W	P-Value	Result
	Day 0	Day 61			
Group A (SG)	15	7	-2.220[a]	0.026	Significant
Group B (CG)	16	9	-2.232[a]	0.026	Significant

Table 07: Results of intra group comparison Day thirty and day sixty one:

	Median		Wilcoxon Signed Rank W	P-Value	Result
	Day 30	Day 61			
Group A (SG)	11	7	-2.214[a]	0.027	Significant
Group B (CG)	11	9	-1.890[a]	0.049	Significant

From above table we can observe that P-Values for both the groups are less than 0.05 thus we can say that there is significant change observed in the scores of day 0 and day 61 for both the groups.
From above table we can observe that P-Values for both the groups are less than 0.05 hence we conclude that there is significant change observed in day 30 and day 61 for both the groups.

Graph 3: Results of intra group comparison: Day thirty and day sixty one:

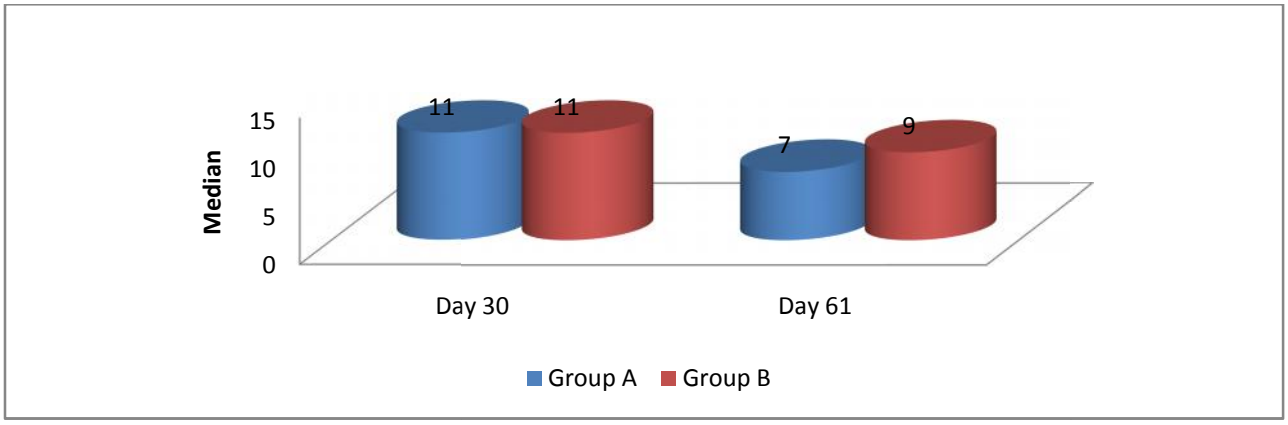
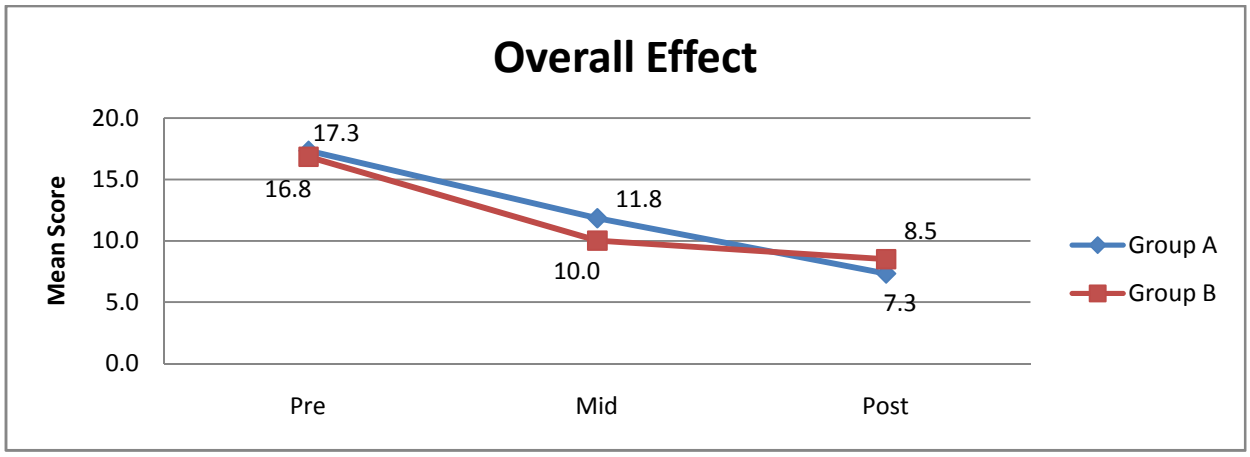


Table 8: Between Group Comparison:

Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value
Group A (SG)	6	7.33	44.00	31.000	0.04
Group B (CG)	6	5.67	34.00		
Total	12				

For comparison between scores of Group A and Group B, Mann Whitney U test was applied. From above table we can observe that P-Value is less than 0.05 thus we can claim that there is significant difference in Group A and Group B.

Graph 4: Overall Effect of study:



Result:

The results are interpreted by considering the above graph, Mean score of Group A decreased from 17.3 to 7.3 within a span of sixty days treatment showing an effect of about 57.6 % while mean score of Group B decreased from 16.8 to 8.5 showing an effect of about 49.5 %. This shows that effect observed in Group A is more than Group B.

DISCUSSION:

Depression is a state of low mood and aversion to activity that can affect a person's thoughts, behaviour, feelings and physical well-being.[4]It is emerging as a dreadful problem being a tough disease to deal with and a challenge for growth and development worldwide. It is considered as an affective disorder characterized by change in mood, lack of interest in the surroundings, psychomotor retardation and melancholia.[5]

The symptoms like *Vishaad, AvasaadandShunyata* can be correlated with the modern aspect of Depression. Thus we can find a correlation between premonitory symptoms of *Unmad* and Depression and it becomes easier to postulate that the drugs acting on *ManovahaSrotas* disorders can be used to treat Depression.

Panchagavyagritha is one among those drugs which is mentioned in *Apasmara* chikitsa.[6] It seems exceedingly useful in various psychiatric conditions mentioned under the term*Unmad*[7].Thus it was evaluated as an adjuvant in the patients of depression.

Here *sneha* means fat or fatty materials and *kalpana* stands for pharmaceutical process of medicaments. Lipid soluble active principle can easily cross the blood brain barrier.[8,9]Lipid soluble drugs have better pharmaco kinetic action in comparison to other dosage forms because of the lipid nature of the biomembranes, as lipid soluble substances rapidly permeate into the cells[10]. *Ghrita* because of its *yogavahiguna*, it incorporates the qualities of the drugs added to it without losing its own qualities. So it is sure that the fat soluble active principles of the drugs added to *ghrita* in *ghritakalpana* can be easily extracted into the *ghrita*[11].

When we assess the five ingredients of *PGG*[12], it is very clear that the drug pacifies three *doshas* with the predominant effect of *Kaphavatashamaka*. It possesses *Agnideepan* and *srotoshodhan* property. (It cleanses the channels in the body). The *srotoshodhana* action of the drug helps to act deeply on the mind destructing the *aavarana* of *tamas* and gives its clarity. Cow curd has *Anulomana* property which results in to alleviation of *vata*. The drug as a whole possesses *Medhya, Ojasyaand Rasaayana* activities. Besides that, the *ghrita* is the best drug for potentiating *dhee, dhritiandsmrithi*, which are the components of *budhi*, as per *Ayurveda*.

All five cow products milk, urine, cow curd, cow dung juice & cow ghee were collected early morning in fresh form so as to maintain the quality of final product. *Desi* Geer breed cows were cradled and nurtured in a natural atmosphere which again ultimately affects the quality of the final product.

For preparation of PGG, steel vessel with a thick bottom was used to avoid any chemical reaction between metal and cow products specially curd and urine. Iron pan was kept below the vessel during last 4-5 hours so as to avoid sticking and burning of Kalka at the last stage of preparation of the formulation and it worked well.

PGG was prepared in duration of total three days so that as per textual reference the final product will possess optimum quality.

After summarizing all the calibre of *PGG*, it can be interpreted that *PGG* may have shown positive Antidepressant activity at the therapeutic dose level, due to above mentioned efficacy.

Patients in group A also displayed much better results in some secondary outcome measures like constipation and insomnia. Patients in group B (conventional therapy) were on either of the treatment Tricyclic antidepressants (TCAs) or Selective Serotonin Reuptake Inhibitors (SSRIs). Side effects of these medicines are constipation & insomnia. As patients in group B did not receive *PGG*, patients in that group showed presence of side effects like constipation & insomnia throughout the study period. As against patients in group A received PGG along with either of the treatment TCA or SSRI and thus displayed remission in these side effects during study period.

CONCLUSION

In present study *PanchgavyaGhrita* proved as a good adjuvant by showing better Antidepressant potential in the patients of depression as compared to conventional therapy.

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