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Study of *Shankhpushpi Ghrita* w.s.r. to it's *Medhya* Activity in Healthy Volunteers

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ABSTRACT

Context: *Shankhapushpi* being the best *Medhya*, has been used in many classical formulations as well as patent preparations for its *Medhya* property. *Go-Ghrita* is a well researched *Medhya Dravya* in Ayurvedic classics. Here is an attempt to compare the *Medhya* effect of *Shankhapushpi Ghrita* (Group A) with *Go-Ghrita*(Group B) in healthy individuals. **Aim:** To evaluate *Medhya* effect of *Shankhapushpi Ghrita* in healthy volunteers. **Methods and Material:** All the raw materials were procured from the departmental pharmacy and the research drug was manufactured in the departmental practical lab. Sixty subjects were randomly selected in each group. Duration of treatment was for 30 days. WMS assessment for memory was carried out on 0 day, 30th day and after 15 days during follow up. **Statistical analysis used:** The results were statistically analysed through Wilcoxon rank test, paired 't' test and unpaired 't' test **Results:** Group A showed improvement in WMS scale when compared to control group. **Conclusions:** The difference in results of group A and B was statistically significant. We may conclude that SG may have better nootropic effect.

Key Words *Medhya, Medha, Wechsler's Memory Scale (W.M.S.),Convolvulus pluricualischoisy*

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INTRODUCTION

Promotion and protection of mental health focuses on creating an environment which promotes healthy living and encourages people to live a healthy lifestyle[1]. Henceforth, it's a intense need to discover the alternate way for the management of the mental imbalances, especially in the developing countries like India. In Ayurveda, vast and detailed description along with the prevention and management of the mental health is explained thoroughly.

Rasayana therapy is rejuvenation therapy, it imparts a physiological and metabolic restoration. *Rasayana* is peculiar class of drugs which are described for prevention and treatment of mental illness in all age groups. In *Samhita Kala* a golden period of *Ayurveda, Acharya* have given much more emphasis to '*Medha*'. Drugs promoting *Medha* are termed as '*Medhya*'. There are number of drugs listed for their *Medhya* effect in our classics among them*Shankhapushpi* is said to be the best *Medhya*drug according to *Acharya Charaka* and is ideally taken in its

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Kalka dosage form. As told by *Acharya Vagbhatta*in *Ashtanga Sangraha*, *Churna*is a type of *Kalka* itself[2].

Innovation of new formulation is the result of experiences of ancient scholars of Ayurveda. Ancient *Acharya* developed number of dosage forms over a period of time whenever there was a need observed.

Recent research works *Shankhapushpi*has been reported to have anxiolytic[3-4], antidepressant[5,6], antioxidant activity[7], brain nourishment activity[8], muscle relaxant[9], learning, memory and behaviour[10-13].

Go-Ghrita is a proven *Medhya* drug in Ayurveda. So, here is an attempt to compare the memory and learning activity of *ShankhapushpiGhrita*(Group A) with standard *Medhya* '*Go-Ghrita'* (Group B) in healthy volunteers through WMS scale.

AIM & OBJECTIVES

Aim- To evaluate the *Medhya* effect of *Shankhapushpi Ghrita* in comparison to *Go-Ghrita* in healthy volunteers.

Objective- To assess the *Medhya* effect using subjective and objective criteria.

MATERIALS AND METHOD

Selection of patients:

Subjects was randomly divided into two groups. Assessment was made based on the research proforma. Since *Go-Ghrita* is a known *Medhya* drug, a separate group was included as a Standard Group in the study. Patients fulfilling inclusion criteria were selected from OPD of Swasthavrutta department of J.S.A.M., Nadiad. All the selected subjects after the registration with necessary information were studied. An informed consent was taken from all subjects included in the present study. These selected patients were divided into two groups by using computerized generated randomization method.

Inclusion criteria:

1. Healthy volunteers between 18-25 years age group will be selected from the surrounding area of research place irrespective to their cast, sex, religion etc.

Exclusion criteria:

1. Age below 16 years and above 25 years.
2. Volunteers having metabolic diseases like Diabetes, Hypertension, other psychotic disorder and other organic pathology.
3. Persons which are *Ayogya*for *Ghrita Pana*.

Study design

Clinico-comparative randomized controlled clinical trial.

- Study type: Interventional
- Masking: Open Label
- Grouping: 2 Groups
- Timing: Prospective
- Sample size: 30 patients in each group

Criteria for assessment

Participants were assessed based on Wechsler's Memory Scale (W.M.S.) (subjective criteria) and haematological and urine routine investigations

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(objective criteria) based on specially designed research proforma through the scoring pattern.

DISCUSSION

Shankhapushpi Ghrita is an *Anumbhuta Yoga* which consists of 3 ingredients wiz. *Go-Ghrita, Shankhapushpi Kwath (Drava Dravya)* and *Shankhapushpi Churna (Kalka)* (Table 1).

Table 1 Ingredients of SG with proportion

Sl no	Ingredients of *Shankhapushpi Ghrita*	Ratio	SG
1	***Shankhapushpi Kalka (ml)***	**1**	3.750
2	***GoGhrita***	**6**	15
3	***Shankhapushpi Kwatha***	**24**	60

Posology

Table 2 Posology of Group A & Group B

Posology	Group A: *Shankhapushpi Ghrita*	Group B: *Go-Ghrita*
Dose	10 gm	10 gm
Frequency	OD	OD
Anupana	Warm water	Warm water
Root of administration	Oral	Oral
Duration	30 Days	30 Days
Follow up	15 Days	15 Days

As mentioned in Table 2, total 10 g of SG and *Go Ghrita* were administered in Group A and Group B respectively on empty stomach with warm water at early morning. In this study, total 60 subjects were enrolled according to inclusion criteria and given *Shankhapushpi Ghrita* (Group A) and *Go-Ghrita* (Group B) for 30 days followed by 15 days of follow up. Before treatment and after treatment, subjective data (Table 3.1-3.8) and objective data (Blood routine and Urine routine) were carried out and assessed statistically with ($p<0.05$) significance.

Table 3.1 Verbal Retention for Similar Pairs

(1)	Verbal Retention for Similar Pairs	Score
1	5 Pair	5
2	4 Pair	4
3	3 Pair	3
4	2 Pair	2
5	1 Pair	1

Table 3.2 Verbal Retention for Dissimilar Pairs

(2)	Verbal Retention for Dissimilar Pairs	Score
1	5 Pair	5
2	4 Pair	4
3	3 Pair	3
4	2 Pair	2
5	1 Pair	1

Table 3.3 Auditory Immediate

(3)	Auditory Immediate	Score
1	23+ Words	5
2	18-22 Words	4
3	13-17 Words	3
4	8-12 Words	2
5	4-7 Words	1

Table 3.4 Auditory Delayed

(4)	Auditory Delayed	Score
1	23+ Words	5
2	18-22 Words	4
3	13-17 Words	3
4	8-12 Words	2
5	4-7 Words	1

Table 3.5 Visual Immediate

(5)	Visual Immediate	Score
1	>= 4 in sequence	5
2	>= 4 not in sequence	4
3	>= 3 in sequence	3
4	>= 2 not in sequence	2
5	1	1

Table 3.6 Visual Delayed

(6)	Visual Delayed	Score
1	>= 13	5
2	10 – 12	4
3	7 – 12	3
4	4 – 6	2
5	1 – 3	1

Table 3.7 Auditory Recognition

(7)	Auditory Recognition	Score
1	1st trial	5
2	2nd trial	4
3	3rd trial	3
4	4th trial	2
5	5th trial	1

Table 3.8 Visual Recognition

(8)	Visual Recognition	Score
1	>9	5
2	7 – 8	4

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3	4 – 6	3
4	3 – 4	2
5	1 – 2	1

Criteria for the overall assessment was fixed as per the percentage of improvement after treatment (Table 4). In the statistical analysis of subjective criteria of Group A (SG), as per Table 5.1, significant improvement observed in all eight criteria i.e. Verbal Retention for Similar pair (13.93%), Verbal Retention for dissimilar pair (51.85%), Auditory Immediate (40.45%), Auditory delayed (41.86%), Visual Immediate (40%), Visual Delayed (35.48%), Auditory Recognition (57.41%) and Visual Recognition (13.11%). Effect of therapy on the Subjective Parameters of Group A (SG) is demonstrated graphically in Chart 1.

Chart 1 Effect of study on the Subjective Parameters of Group A (SG)

Objective criteria:
Haematological Investigations & Urine routine Investigations

Table 4 Criteria for total improvement for overall assessment

No.	Total improvement	Criteria
1	Complete improvement	< 100 % improvement in assessment criteria
2	Marked improvement	< 75 % improvement in assessment criteria
3	Moderate improvement	< 50 % improvement in assessment criteria
4	Mild improvement	< 25 % improvement in assessment criteria
5	No improvement	No improvement in assessment criteria

While, Group B *(Go-Ghrita)* also showed statistically significant improvement in all seven criteria except 1st criteria i.e. Verbal retention for similar pairs (Table 5.2). The results of Group B can be compared graphically as shown in Chart 2 showing the statistical difference in results before and after study.

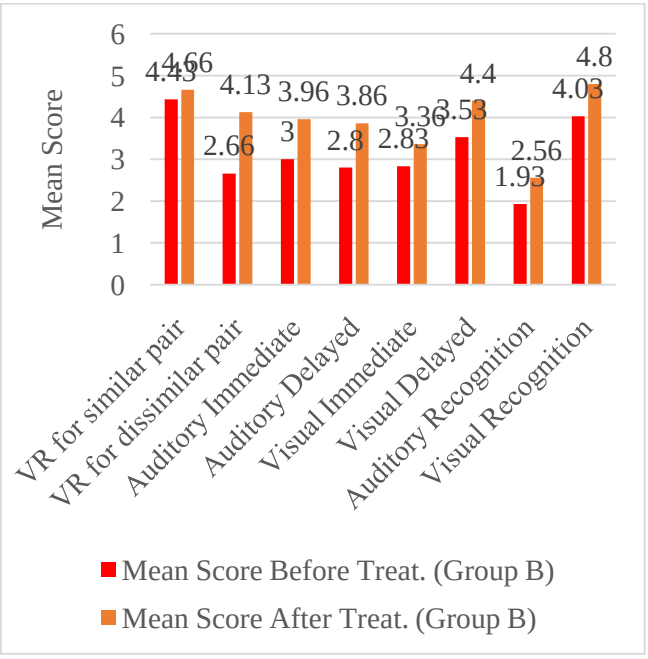

Chart 2 Effect of study on the Subjective Parameters of Group B (*Go-Ghrita*)

Subjective criteria:

Table 5.1 Effect of therapy on the Subjective Parameters of Group A -SG [Wilcoxon matched-pairs signed rank test]

Chief Complaints	Group	N	BT (Mean±	AT (Mean±	%	Sum of All Ranks	P	Result

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			S.D.)	S.D.)		(W)		
VR for similar pair	A	30	4.06 ± **0**.86	4.63 ± 0.85	13.93	139	0.003	< 0.05 Significant
VR for dissimilar pair	A	30	2.70 ± 1.31	4.10 ± 0.99	51.85	231	0.000	< 0.05 Significant
Auditory Immediate	A	30	2.96 ± 0.85	4.16 ± 0.69	40.45	276	0.000	< 0.05 Significant
Auditory Delayed	A	30	2.86 ± 0 .86	4.06 ± 0.63	41.86	276	0.000	< 0.05 Significant
Visual Immediate	A	30	2.50 ± 1.25	3.50 ± 1.16	40	242	0.000	< 0.05 Significant
Visual Delayed	A	30	3.10 ± 0.75	4.20 ± 0.61	35.48	300	0.000	< 0.05 Significant
Auditory Recognition	A	30	1.80 ± 0.71	2.83 ± 0.64	57.41	253	0.000	< 0.05 Significant
Visual Recognition	A	30	4.06 ± 0.69	4.60 ± 0.56	13.11	138	0.003	< 0.05 Significant

Results of subjective criteria of Group A when compared to standard Group B, statistically significant difference was observed in Auditory Recognition (p= 0.038, <0.05 significant level) (Table 6.1). As per the details of chart 3, it can be observed that Group A showed better Medhya effect than standard group B for most of the subjective criteria of WMS scale except for the auditory recognition. Though statistically difference was not found in other seven criteria, percentage wise difference was notable proving that SG may have better *Medhya* effect than Go-*Ghrita*. Hence, SG can a better choice of drug when auditory recognition is expected. From the results of objective criteria, it is observed that statistically the difference is nonsignificant for both the group in blood routine and urine routine investigations (Table 6.2.- 6.3).

Table 5.2 Effect of therapy on the Subjective Parameters of Group B [Wilcoxon matched-pairs signed rank test]

Chief Complaints	Group	N	BT (Mean± S.D.)	AT (Mean± S.D.)	%	Sum of All Ranks (W)	P	Result
VR for similar Pair	B	30	4.43 ± 0.77	4.66 ± 0.54	5.26	67	0.106	> 0.05 Not Significant
VR for dissimilar pair	B	30	2.66 ± 1.51	4.13 ± 0.97	55.00	300	0.000	< 0.05 Significant
Auditory Immediate	B	30	3.00 ± 0.90	3.96 ± 0.76	32.22	231	0.000	< 0.05 Significant
Auditory Delayed	B	30	2.8 ± 1.03	3.86 ± 0.73	38.10	276	0.000	< 0.05 Significant
Visual Immediate	B	30	2.83 ± 1.03	3.36 ± 0.99	18.82	154	0.015	< 0.05 Significant
Visual Delayed	B	30	3.53 ± 0.81	4.40 ± 0.85	24.53	223	0.000	< 0.05 Significant
Auditory Recognition	B	30	1.93 ± 0.73	2.56 ± 0.77	32.76	153	0.000	< 0.05 Significant
Visual Recognition	B	30	4.03 ± 0.55	4.80 ± 0.40	19.01	222	0.000	< 0.05 Significant

Table 6.1 Intergroup comparison of subjective criteria

Chief Complaints	N	Group A (%)	Group B (%)	Mann Whitney U	Resulted 'P'	Result
VR for similar Pair	30	13.93	5.26	247.50	0.165	Not Significant
VR for dissimilar pair	30	51.85	55.00	446.00	0.951	Not Significant

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Auditory Immediate	30	40.45	32.22	366.50	0.188	Not Significant
Auditory Delayed	30	41.86	38.10	382.50	0.286	Not Significant
Visual Immediate	30	40	18.82	385.00	0.309	Not Significant
Visual Delayed	30	35.48	24.53	373.50	0.222	Not Significant
Auditory Recognition	30	57.41	32.76	320.5	0.038	Significant
Visual Recognition	30	13.11	19.01	372.5	0.213	Not Significant

Table 6.2 Effect of therapy on the Hematological and urine Investigations (Objective Parameters) of group A [Paired t Test]

Hematological and Bio-Chemical Investigations	**Group**	**N**	**BT (Mean ± S.D.)**	**AT (Mean ± S.D.)**	**Mean Change**	**%**	**t value**	**P value**	**Result**
Hb%	A	30	11.95 ± 1.94	12.25 ± 1.77	.30 ± 0.97	2.51	1.68	0.102 (>0.05)	Not Significant
ESR	A	30	9.67 ± 4.68	9.10 ± 4.64	0.57 ± 3.99	5.86	0.776	0.444 (>0.05)	Not Significant
Neutrophil Count	A	30	61.20 ± 7.58	59.16 ± 7.50	2.03 ± 8.35	3.32	1.33	0.193 (>0.05)	Not Significant
Lymphocytes	A	30	31.86 ± 8.32	33.23 ± 8.15	1.36 ± 7.25	5.05	1.032	0.311 (>0.05)	Not Significant
Eosinophil Count	A	30	1.80 ± 1.34	1.96 ± 1.37	0.16 ± 1.74	9.26	0.524	0.605 (<0.05)	Not Significant
Monocytes	A	30	5.80 ± 2.36	5.96 ± 2.04	0.16 ± 2.08	2.87	0.438	0.665 (>0.05)	Not Significant
Urine Specific Gravity	A	30	1.01 ± 0.00	1.01 ± 0.00	0.001 ± 0.00	0.03	0.220	0.827 (>0.05)	Not Significant

Table 6.3 Effect of therapy on the Hematological and urine Investigations (Objective Parameters) of group B [Paired t Test]

Hematological and Bio-Chemical Investigations	**Group**	**n**	**BT (Mean ± S.D.)**	**AT (Mean ± S.D.)**	**Mean Change**	**%**	**t value**	**P value**	**Result**
Hb%	B	30	12.30 ± 1.87	12.43 ± 1.73	0.13 ± 0.58	1.06	1.21	0.236 (>0.05)	Not Significant
ESR	B	30	9.90 ± 5.96	9.46 ± 4.31	.43 ± 4.43	4.38	.535	0.597 (>0.05)	Not Significant
Neutrophil Count	B	30	59.50 ± 7.27	58.93 ± 7.96	.56 ± 9.73	.95	.319	0.752 (>0.05)	Not Significant
Lymphocytes	B	30	32.73 ± 6.74	32.40 ± 7.64	.33 ± 9.10	1.02	0.20	0.843 (>0.05)	Not Significant
Eosinophil Count	B	30	1.83 ± 1.11	1.86 ± 1.52	.03 ± 1.54	1.82	.118	0.907 (>0.05)	Not Significant
Monocytes	B	30	5.63 ± 1.58	6.80 ± 2.52	1.16 ± 2.35	20.71	2.71	0.011 (>0.05)	Not Significant
Urine Specific Gravity	B	30	1.01 ± 0.00	1.01 ± 0.0	0.00 ± 0.00	0.13	.955	0.348 (>0.05)	Not Significant

Table 6.4 Overall assessment of therapy

Overall Assessment	**Group A (n=30)**		**Group B (n=30)**	
	N	%	N	%
Complete Improvement	0	0	0	0
Marked Improvement	0	0	0	0
Moderate Improvement	11	36.66	6	20
Mild Improvement	18	60	24	80
No Improvement	1	3.33	0	0

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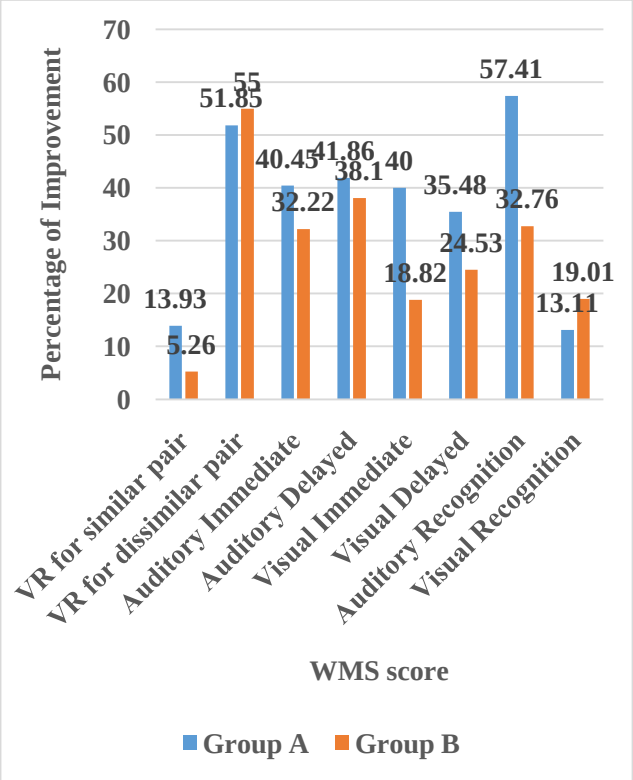

Chart 3 Effect of study (Subjective Parameters) for Intergroup Comparison

After overall assessment of both therapies, it can be concluded that 36% (11) of participants showed moderate improvement in Group A. While, 80% (24) of subjects showed mild improvement in Group B (Table 6.4).

Since no negative CP drug interaction is reported till date, more studies in this regard remain to be completed. A research model involving multiple approach by linking CP and other herbal *Medhya* drugs will be highly desirable.

Probable Mode of Action:

The *Medhya* effect of *Shankhapushpi* can be considered as *Prabhava Janya* (unthinkable and unimaginable). This attribution holds good since the action of *Medhya Dravya* cannot be related to a particular quality of the drug. Maintaining of normal functioning of *Sadhaka Pitta* and *Tarpaka Kapha* is the desired action. *Medhya* drugs also act on *Manasika Bhavas* (faculties of mind) there by improving memory functions, relieving anxiety, stress etc. They are having *Mastishka Balya* (nourishing brain) property. It is very difficult to conclude the mode of action of *Medhya Rasayanas* as the mechanism of *Medha* is very complex one and will need higher systems of examinations to prove the pharmacodynamics and pharmacokinetics.

CONCLUSION

Promotion of mental health is the need of the current society. Ayurveda a holistic science provides many herbal compounds for memory related disorders in a better way. *Shankhapushpi Ghrita* being such novel formulation showed significant result in improving memory as assessed by WMS scale after treatment of 30 days. On comparing to standard (*Go-Ghrita*), the results of Auditory Recognition were statistically significant in SG. Thus, the study can conclude that SG can be a potent memory booster tonic for school and college going students. Future experiments involving large sample size and in depth cause-effect evaluations would be more confirmatory.

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