

A HEALTHY VOLUNTEER STUDY OF *SHANKHAPUSHPI* GRANULES W.S.R. TO ITS
MEDHYA ACTIVITY*¹Dr. Dhatri Umraniya R. and ²Dr. U. U. Zala¹Ph.D. Scholar, PG Dept. of Rasashastra Evam Bhaishajya Kalpana, J.S. Ayurved Mahavidyalaya.²Professor & H.O.D., PG Dept. of Rasashastra Evam Bhaishajya Kalpana, J.S. Ayurved Mahavidyalaya.

*Corresponding Author: Dr. Dhatri Umraniya R.

Ph.D. Scholar, PG Dept. of Rasashastra Evam Bhaishajya Kalpana, J.S. Ayurved Mahavidyalaya.

Article Received on 07/06/2022

Article Revised on 27/06/2022

Article Accepted on 17/07/2022

ABSTRACT

Context: *Shankhapushpi* being the best *Medhya*, has been used in many classical formulations as well as patent preparations for its *Medhya* property. Here is an attempt to assess the *Medhya* effect of *Shankhapushpi* Granules in healthy individuals. **Aims:** To evaluate *Medhya* effect of *Shankhapushpi* Granules 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. 30 Subjects were randomly selected in the study. 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. **Results:** *Shankhapushpi* Granules showed improvement in all eight criteria of WMS scale. **Conclusions:** The maximum improvement was observed in Verbal retention for dissimilar pair and Auditory delayed. The SGr can be a drug of choice where these type of memory is expected to improve.

KEYWORDS: *Medhya*, *Medha*, Wechsler's Memory Scale (W.M.S.), *Convolvulus pluricualis choisy*.

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

Abbreviations

SYC- *Shankhapushpi Yavakuta Churna*SK-
*Shankhapushpi Kwatha*SC- *Shankhapushpi Churna*SGr- *Shankhapushpi Granule*

W.M.S. – Wechsler's Memory Scale

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]

It is the need of an hour to formulate such novel dosage forms which are easily portable, having longer shelf life and patient friendly. So, here is an attempt to assess the memory and learning activity of *Shankhapushpi* Granules in healthy volunteers through WMS scale.

AIM & OBJECTIVE

Aim- To evaluate the *Medhya* effect of *Shankhapushpi* Granules in healthy volunteers.Objective- To assess the *Medhya* effect using subjective and objective criteria.

MATERIALS AND METHOD

Preparation of Drug (SGr)

The raw material was procured from departmental pharmacy. After finalizing the batch from pilot batches, *Shankhapushpi* Granules were prepared in practical lab

of Dept. of RSBK. Equal quantity of SK and *Sharkara* were taken and heated till the 2.5 thread consistency. After taking off from fire, SC was added to the mixture and granules were prepared by passing it through 10# sieve.

Table 1: Ingredients of SGr with proportion.

Sl no	Ingredients of <i>Shankhapushpi</i> Granules	Ratio	SG
1	<i>Shankhapushpi Churna</i>	1	3.750
2	<i>Shankhapushpi Kvatha</i>	4	15
3	<i>Sharkara</i>	4	15

Selection of patients

Healthy subjects were randomly chosen. Assessment was made based on the research proforma. 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.

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.

Inclusion criteria

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.

Treatment protocols

Posology

Table 2: Posology of SGr.

Posology	<i>Shankhapushpi</i> Granules
Dose	6 gm
Frequency	OD
Anupana	Warm water
Root of administration	Oral
Duration	30 Days
Follow up	15 Days

Study design

Clinico-comparative randomized controlled clinical trial.

- Study type: Interventional
- Masking: Open Label
- Grouping: 1 Groups
- Timing: Prospective
- Sample size: 30 patients

Criteria for assessment

Participants were assessed based on Wechsler's Memory Scale (W.M.S.) (subjective criteria) and haematological & urine routine investigations (objective criteria) based on specially designed research proforma through the scoring pattern.

Ethical Committee approval No: J.S.A.M./IECHR /110/01-2020 (Dated 11/07/2020)

Subjective criteria

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
3	4 – 6	3
4	3 – 4	2
5	1 – 2	1

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

RESULT

Subjective criteria

Table 5.1: Effect of therapy on the Subjective Parameters [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	2.80 ± 1.09	3.43 ± 1.04	22.62	205	0.008	< 0.05 Significant
VR for dissimilar pair	B	30	3.30 ± 1.02	4.50 ± 0.57	36.36	276	0.000	< 0.05 Significant
Auditory Immediate	B	30	2.03 ± 0.76	2.66 ± 0.75	17.58	120	0.000	< 0.05 Significant
Auditory Delayed	B	30	2.80 ± 0.80	3.43 ± 0.72	22.62	13	0.001	< 0.05 Significant
Visual Immediate	B	30	2.80 ± 1.09	3.43 ± 1.04	22.62	205	0.017	< 0.05 Significant
Visual Delayed	B	30	3.30 ± 1.02	4.50 ± 0.57	36.36	276	0.000	< 0.05 Significant
Auditory Recognition	B	30	2.03 ± 0.76	2.66 ± 0.75	31.15	120	0.000	< 0.05 Significant
Visual Recognition	B	30	4.06 ± 0.75	4.80 ± 0.16	18.03	147	0.001	< 0.05 Significant

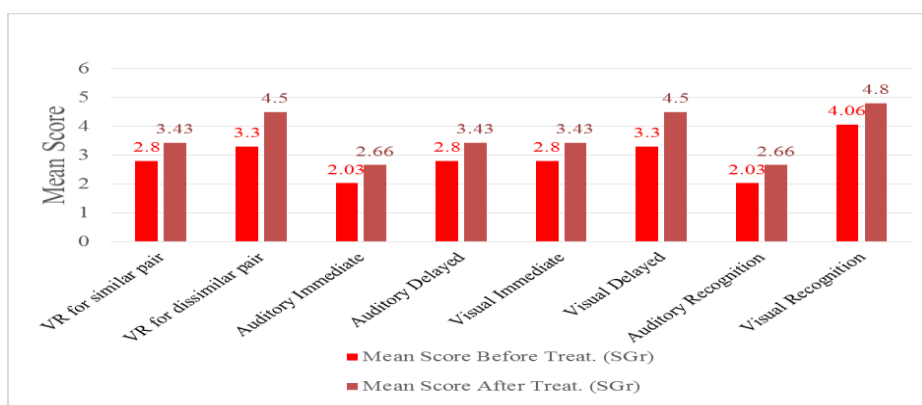


Chart 1: Effect of therapy on the Subjective Parameters.

Objective Criteria

Table 5.2: Effect of therapy on the Hematological and urine Investigations (Objective Parameters) [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	11.97 ± 2.58	12.45 ± 2.04	.48 ± 1.78	4.04	1.487	.148 (>0.05)	Not Significant
ESR	A	30	7.46 ± 3.24	7.23 ± 2.67	.23 ± 2.11	3.13	0.605	.550 (>0.05)	Not Significant
Neutrophil Count	A	30	58.16 ± 7.42	56.43 ± 7.86	1.73 ± 8.21	2.98	1.156	.257 (>0.05)	Not Significant
Lymphocytes	A	30	34.36 ± 6.48	35.73 ± 6.47	1.36 ± 7.48	3.01	1.00	.326 (>0.05)	Not Significant
Eosinophil Count	A	30	2.06 ± 1.79	2.40 ± 1.58	.33 ± 1.53	16.13	1.186	.245 (<0.05)	Not Significant
Monocytes	A	30	6.00 ± 1.92	5.93 ± 2.24	.06 ± 2.30	1.11	0.159	.875 (>0.05)	Not Significant
Urine Specific Gravity	A	30	1.00 ± 0.00	1.01 ± 0.00	.05 ± .01	0.10	0.546	.589 (<0.05)	Not Significant

Table 5.3 Overall assessment of therapy.

Overall Assessment	SGr (n=30)	
	N	%
Complete Improvement	0	0
Marked Improvement	0	0
Moderate Improvement	08	26.66
Mild Improvement	20	66.66
No Improvement	0	0

DISCUSSION

Shankhapushpi Granule is an *Anumbhuta Yoga* which consists of 3 ingredients viz. *Sharkara (Madhura Dravya)*, *Shankhapushpi Kwath (Drava Dravya)* and *Shankhapushpi Churna (Prakshepa)* (Table 1). As mentioned in Table 2, total 6 g of SGr was administered on empty stomach with warm water at early morning. In this study, total 30 subjects were enrolled according to inclusion criteria and given *Shankhapushpi* Granule (SGr) 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.

Criteria for the overall assessment was fixed as per the percentage of improvement after treatment is as shown in Table 4. In the statistical analysis of subjective criteria of SGr, as per Table 5.1, significant improvement observed in all eight criteria is observed i.e. Verbal Retention for Similar pair (22.62%), Verbal Retention for dissimilar pair (36.36%), Auditory Immediate (17.58%), Auditory delayed (22.62%), Visual Immediate (22.62%), Visual Delayed (36.36%), Auditory Recognition (31.15%) and Visual Recognition (18.03%). Effect of therapy on the Subjective Parameters of Group A (SG) is demonstrated graphically in Chart 1. From the results of all eight criteria, SGr showed maximum improvement in verbal

retention for dissimilar pair (36.3%) and visual delayed (36.36%).

As shown in Table 5.2, it is observed that statistically the difference is nonsignificant for the objective criteria i.e. blood routine and urine routine investigations.

After overall assessment of both therapies, as shown in Table 5.3, it can be concluded that 26.26% (08) of participants showed moderate improvement. While, 66.66% (20) of subjects showed mild improvement.

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* Granules being such novel formulation showed significant result in improving memory as assessed by WMS scale after treatment of 30 days. The maximum improvement was observed in Verbal Retention for dissimilar Pair and Auditory Delayed. Thus, the study can conclude that SGr can be a potent memory booster tonic for school going children especially where verbal retention power as well as auditory memory is expected to improve. Future experiments involving large sample size and in depth cause-effect evaluations would be more confirmatory. Other higher techniques like Brain Mapping etc can be made use of for confirmative results.

REFERENCES

1. World Health Organization, Health in India [Homepage on internet]. Available from:
2. http://www.searo.who.int/india/topics/mental_health/about_mentalhealth/en/ Reviewed on Date, 21/04/2019.
3. Ashtanga Sangraha of Vagbhatt, translated by Prof. K.R.Srikantha Murthy, Chaukhambha orientalia, Varanasi, Edi, 2005; 2: A.S.Ka.8/10, p-618.
4. Prasad GC, Gupta RC, Srivastava DN, Tandon AK, Wahi RS, Udupa KN. Effect of Shankhpushpi on experimental stress. *J Res Indian Med*, 1974; 9: 19-27.
5. Singh RH, Mehta AK. Studies on the psychotropic effect of the Medhya Rasayana drug 'Shankhpushpi' (Convolvulus pluricaulis) part 1 (Clinical Studies). *J Res Ind Med Yog Homeo*, 1977; 12: 18.
6. Shukla SP. A comparative study on the barbiturate hypnosis potentiation effect of medhya rasayana drugs shankhapushpi (Convolvulus pluricaulis). *BMEBR*, 1981b; 1: 554.
7. Nahata A, Patil UK, Dixit VK. Anxiolytic activity of Evolvulus alsinoides and Convolvulus pluricaulis in rodents. *Pharm Biol*, 2009; 47: 444-51.
8. Dhingra D, Valecha R. Evaluation of the antidepressant like activity of Convolvulus pluricaulis in the mouse forced swim and tail suspension tests. *Med Sci Monit*, 2007; 13: 155-61.
9. Chaturvedi M, Mali PC, Dixit VP. Hypolipidaemic effect of Convolvulus microphyllus on cholesterol fed gerbils.
10. Dandiya PC. The pharmacological basis of herbal drugs acting on CNS. *Eastern Pharm*, 1990; 33: 39-47.
11. Manyam MD. Dementia in Ayurveda. *J Altern Complement Med*, 1999; 5: 81-8.
12. Prasad GC, Gupta RC, Srivastava DN, Tandon AK, Wahi RS, Udupa KN. Effect of Shankhapushpi on experimental stress. *J.Res Indian Med*, 1974; 9: 19-27.
13. Deshpande SM, Srivastava DN. Chemical examination of the fatty acids of convolvulus pluricaulis. *Indian Oil Soap J*, 1969; 34: 217-8.
14. Nahat A, Patil UK, Dixit VK. Effect of Convolvulus pluricaulis Choisy. On learning behaviour and memory enhancement activity in rodents. *Nat Prod Res*, 2008; 22: 1472-82.