

CLINICAL EVALUATION OF RASAYANA EFFECT OF ASHWAGANDHADILEHYA IN
APPARENTLY HEALTHY ELDERLY PERSONS

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ABSTRACT

The number of aged persons is steadily increasing all over the world. Improvement in social condition, change in life style & better health status during the past few decades have increased the life span of men as well as the number of elderly persons all over the world. With the growing number of elderly individuals in today's society, the health problems of old age are becoming more and more overt. Accordingly, geriatrics is emerging as a major medical specialty all over the world. The strength of Ayurveda in the context of geriatrics is Rasayana therapy, it is a unique approach because of its ability to promote longevity and influence all aspects of health in a positive way. The main utility of Rasayana therapy is in functional and degenerative disorders that have a chronic or long standing nature. Rasayana helps to maintain good health and to establish impaired physical or mental health in elderly people. In the present single group open trial for 3 months 50 apparently healthy elderly persons were evaluated to evaluate the Rasayana effect of Ashwagandhadilehya. The trial drug was administered 10gm twice daily with lukewarm milk for three months the volunteers were assessed using primary and secondary criteria. The assessment was done on every 14th day. The last follow up was done after one month of the completion of trial. At the end of trial significant results were found and the efficacy and safety of Ashwagandhadilehya as a Rasayana in elderly persons was proved.

KEYWORDS: Geriatrics, Rasayana, Ashwagandhadilehya.

INTRODUCTION

Ayurveda gives top priority to geriatrics. Geriatrics is that branch of medicine concerned with the care and treatment of elderly. Geriatric problems are multifactorial in nature. The major challenge is to understand and promote the factors that keep people healthy, as they grow older. Based on fundamental laws of nature *Ayurveda* propound a highly evolved science of life, health and cure, the concept of ageing and Rasayana finds a prominent place. *Rasayana* drugs are the substances that support *Rasa* and stimulate the production of *Ojas*.^[1] Thus in old people *Rasayana* promotes longevity, memory, intelligence, freedom from disease, youthfulness, excellence of luster. Various studies showed the free radical scavenging and antiageing effect of *Rasayana*. *Rasayana* is not a single drug it bears wide coverage on the drug, diet and discipline. It is achieved by *Achara Rasayana*, *Ahar Rasayana* and *Dravya Rasayana*. *Rasayana* acclaimed for *Swasthya Oorjaskar*, *Vyadhihara* and prevent *Jara*. Treatment of *Jara* associated problems with *Rasayana* and other medications is possible to improve the quality of life to some extent. *Rasayana* therapy ensures long life. An ideal *Rasayana* prolongs life, improves memory and intellect, promotes health, and provides immunity

against diseases thereby helps an individual to lead an energetic life. It improves lustre and complexion of the body, tones the voice and speech, and increases the acuity of all the sensory and motor organs, vitality and vigour.^[2]

MATERIAL AND METHOD

About the drug

In the present study *Ashwagandhadilehya*,^[3] has been taken to evaluate its *Rasayana* effect. There are so many references available in the *Ayurvedic* classics regarding *Rasayana* properties of ingredients of *Ashwagandhadilehya* (*Ashwagandha*, *Sariva*, *Jeeraka*, *Madhushuni*, *Draksha* and *ela*). These *Rasayana* properties have proven Adaptogenic, Anti-Inflammatory, Antioxidant, Free Radical Scavenging, Immuno-Modulator activities and play a major role in the management of free radical mediated injury in the body and thus may be helpful to delay ageing process.

The present study is a part of *Ayurveda* Clinical Trials (ACT) Project of Ayurvedic Pharmacopoeia Committee (ACP), conducted by CCRAS on the topic "*Clinical Evaluation of Rasayana Effect of Ashwagandhadilehya In Apparently Healthy Elderly Persons*". The

drug was prepared in *Goghrita* as per following the rules and regulations of 'Avlehya Kalpana' manufactured by

Dabur Research and Development Centre, 22 Site 4, Ghaziabad, U.P. India.

Ingredients of Ashvagandhadi Lehya

Ashvagandhadi Lehya contain many plant and animal origin drugs, following table shows their botanical name, part use, proportion and percentage. (Table no.1)

Sr. No.	Sanskrit Name	Botanical Name	Parts Used	Proportion	%age
1.	Ashwagandha	Withania somnifera	Root, Leaves, Fruit	192gm	6.36
2.	Sariva	Hemidiscus indicus	Root	192 gm	6.36
3.	Jiraka	Cuminum cyminum	Seed	192 gm	6.36
4.	Madhusnuhi	Smilax china	Rhizome	192 gm	6.36
5.	Draksha	Vitis vinifera	Fruits	192 gm	6.36
6.	Ela	Elettaria cardamonum	Seed	24 gm	0.79
7.	Goghrita			226 gm	7.488
8.	Madhu			452 gm	14.97
9.	Sharkara			1.356 kg	44.9
10.	Water			452	

(Dose: 10 gm BD Anupana: Lukewarm Milk)

Plan of Study

The present study was carried out to evaluate the *Rasayana* effect of *Ashwagandhadilehya* in apparently healthy elderly persons. Total 50 volunteers were selected for the study.

Inclusion Criteria

1. Apparently Healthy Males / Females of age between 50 and 75 years.
2. Willing and able to participate for 16 weeks.

Exclusion Criteria

1. Volunteers with evidence of malignancy.
2. Volunteers suffering from major systemic illness necessitating long term drug trial (Rheumatoid arthritis, Psycho-Neuro-Endocrinal disorders, etc.)
3. Volunteers who have a past history of Atrial Fibrillation, Coronary Artery Disease (CAD), Acute Coronary Syndrome, Myocardial Infarction, Stroke or Severe Arrhythmia in the last 6 months.
4. Symptomatic volunteer with clinical evidence of Heart failure.
5. Volunteers with poorly controlled Hypertension (> 160 / 100 mm Hg).
6. Volunteers on prolonged (> 6 weeks) medication with corticosteroids, antidepressants, anticholinergics, etc. or any other drugs that may have an influence on the outcome of the study.
7. Volunteers with concurrent serious hepatic disorder (defined as Aspartate Amino Transferase (AST) and/or Alanine Amino Transferase (ALT), Total Bilirubin, Alkaline Phosphatase (ALP) > 2 times upper normal limit) or Renal Disorders (defined as S. Creatinine >1.2mg/dL).
8. Volunteers with severe Pulmonary Dysfunction (uncontrolled Bronchial Asthma and / or Chronic Obstructive Pulmonary Disease [COPD]), Inflammatory Bowel Disease, Severe Dementia, Severe Infection(s), Non-ambulatory volunteer or any other condition that may jeopardize the study.

9. Prostate Specific Antigen (PSA) levels > 4 ng/mL
10. Alcoholics and/or drug abusers.
11. Pregnant / lactating woman.
12. Volunteers suffering from Diabetes Mellitus {B.S. (F) > 126 mg% and / or B.S. (2 hr. PP) >200 mg% or HbA1c > 6.5% }.
13. H/O hypersensitivity to the trial drug or any of its ingredients.
14. Volunteers who have completed participation in any other clinical trial during the past six (06) months.
15. Any other condition which the Principal Investigator thinks may jeopardize the study.

Criteria for Assessment

Primary Assessment Criteria

1. Change in the clinical symptoms (using the Visual Analogue Scale).
2. Change in Quality of life using WHO-QOL-BREF

Secondary Assessment Criteria

1. Change in Hamilton Depression Rating Scale(HDRS) Score
2. Change in PGI Memory Scale score.
3. Change in the Laboratory parameters (markers for ageing).
 - ESR
 - Serum Cholesterol
 - High Density Lipoprotein (HDLc)
 - Low Density Lipoprotein (LDLc)

Methods of Assessment

Prior to selection – (Screening)

1. Informed Consent
2. Eligibility evaluation
3. Physical examination
4. Laboratory investigations

During Selection-(Baseline)

1. General information-(Personal Identification & Demographic profile)

2. Medical history , General Physical and Systemic examination
3. Assessment of Clinical / Ayurvedic Parameters
4. Hamilton Depression Rating Scale Score
5. PGI Memory scale score.
6. WHO QOL BREF Score.
7. Issue of drugs
8. Instructions to come after 2 weeks (14 days).

During trial i.e. on 14th day, 28th day, 42nd day, 56th day and 70th day the volunteer were screened as per follows

1. Physical examination and clinical assessment
2. Hamilton Depression Rating Scale Score. (on **28th day, 56th day**)
3. PGI Memory Scale Score (on **28th day, 56th day**)
4. Assessing drug compliance
5. Issue of drugs.
6. Instructions to come after 2 weeks (14 days).

At the end of the trial i.e. at the end of 12 weeks (84th day) the volunteer were screened as per follows:

1. Assessment of Clinical / Ayurvedic Parameters
2. Physical examination and clinical assessment.
3. Hamilton Depression Rating Scale Score
4. PGI Memory Scale score
5. WHO- QOL BREF Score.
6. Laboratory Investigations.
7. Assessing drug compliance.
8. Instructions to come after 4 weeks

Assessment at the end of 16 weeks the volunteer were screened as per follows

1. Clinical Assessment
2. Hamilton Depression Rating Scale Score
3. PGI Memory Scale score
4. WHO QOL BREF Score

Laboratory Investigations

The following laboratory investigations were carried out before and after trial. (Table no.2).

Sr. no.	Hematological tests	Biochemical tests
1.	Hemoglobin (Hb)	Blood urea
2.	Total leucocyte count	Serum uric acid
3.	Differential leucocyte count	S.G.O.T.
4.	Erythrocyte sedimentation rate	S.G.P.T.
5.	Fasting blood sugar	Total proteins
6.		S. albumin
7.		S. globulin
8.		A/G ratio
9.		S. bilirubin
10.		S. alkaline phosphate
11.		Lipid profile

RESULTS AND DISCUSSION

The results observed from this clinical study are presented as follows:

Effect of Ashwagandhadilehya on Visual analogue scale: (Table no.3)

Sr. no.	Symptom	BT(MEAN)	AT(MEAN)	P VALUE
1.	Dizziness	15.00	1.00	<.001
2.	Constipation	43.5	.50	<.001
3.	Urge incontinence	3.50	.50	<.05
4.	Ache muscle	29.5	3.5	<.001
5.	Joint pain	50.50	24.00	<.001
6.	Joint stiff	40	15.00	<.001
7.	Abnormal Sleep	24.50	00	<.001
8.	Loss of appetite	25.50	00	<.001
9.	Fatigue	53.50	5.0	<.001
10.	Gen. weakness	52.0	6.5	<.001
11.	Well being	64.5	99.5	<.001

(BT- before trial, AT – after trial)

At the end of the trial the effect of Ashwagandhadilehya on visual analog scale the parameters are showing highly significant relief in dizziness, constipation, urge incontinence, aching muscles, joint pain, joint stiffness,

loss of appetite, disturbed sleep, fatigue, generalized weakness and also increase in sense of well being.

Effect of Ashwagandhadilehya on Hemilton Depression Rating Scale: (Table no.4)

Sr. no.	Mean score		% Relief	SD±	SE±	T	P
	BT	AT					
	0 th day	84 th day					
1.	9.30	4.44	52.25%	3.71	0.526	9.23	<.001

(BT- before trial, AT – after trial)

The mean score of HDRS before trial was 9.3 which reduced to 4.44 at end of trial. 52.25% relief was observed. SD±3.71, SE± .526 and the result was highly

significant with 't' value of 9.23 (P<.001). The effect was stable after one month follow up.

Effect of Ashwagandhadilehya on PGI Memory Scale: (Table no. 5)

Sr. no.	Mean score		% Relief	SD±	SE±	T	P
	BT	AT					
	0 th day	84 th day					
1.	66.62	70.78	6.24%	6.07	0.859	4.84	<.001

(BT- before trial, AT – after trial)

The mean score of PGI memory scale before trial was 66.62 which increased up to 70.78 at end of trial. 6.24% relief was observed, SD±6.07, SE± .859 and the effect

was statistically highly significant with 't' value of 4.84 (P<.001) The effect was stable after one month follow up.

Effect of Ashwagandhadilehya on WHO-QOL BREF: (Table No.6)

WHO-QOL BREF	Mean Score		% Relief	SD±	SE±	T	P
	BT	AT					
D1	20.14	21.46	6.55%	1.98	0.280	4.704	<.001
D2	17.28	18.84	9.02%	2.01	0.284	5.48	<.001
D3	9.36	9.34	0.21%	1.86	.26	.076	>.05
D4	24.26	26.26	8.24%	4.63	.655	3.05	<.05

(BT- before trial, AT – after trial)

The mean score before and after the trial indicate positive increment in WHO-QOL BREF. The effect was stable after one month of follow up.

Effect of Ashwagandhadilehya on Lab. Parameters: (Table no. 7)

Sr. no.	Variables	Mean Score		SD±	SE±	T	P
		BT	AT				
1.	Hb (gm%)	11.58	12.47	0.93	0.131	6.801	<.001
2.	Total proteins	6.87	9.54	12.82	1.81	1.47	>.05
3.	Blood Urea mg/dl	34.5	32.56	4.86	0.687	2.851	<.05
4.	Serum Uric acid mg/dl	6.274	6.16	8.86	1.254	0.091	>.05
5.	FBS	91.34	88.58	10.03	1.41	1.94	>.05
6.	ESR	11.12	16.12	23.87	3.37	1.48	>.05
7.	Serum Creatinine	0.836	0.784	0.19	0.02	1.89	>.05
8.	SGOT	33.68	30.64	10.39	1.47	2.06	<.05
9.	SGPT	38.28	34.24	11.40	1.61	2.50	<.05
10.	Conjugated Bilirubin	0.45	0.36	0.22	0.03	2.66	<.05
11.	Unconjugated Bilirubin	0.31	0.26	0.18	0.02	1.85	>.05
12.	Alkaline Phosphatase	80.10	78.30	17.08	2.41	0.745	>.05

(BT- before trial, AT – after trial)

At the end of the trial there was statistically significant increase (p<0.001) in Hb% where as statistically significant reduction (p<0.05) was observed in values of blood urea, SGOT, SGPT & conjugated bilirubin but in the value of fasting blood sugar, differential leucocyte

count, ESR, Serum creatinine, serum alkaline phosphatase & total proteins there is no statistically significant (P>.05) changes was observed.

Effect of Ashwagandhadilehya on Lipid Profile: (Table no. 8)

Sr. No.	Lipid Profile	Mean Score		SD±	SE±	t	P
		BT	AT				
1.	Cholesterol	188.22	166.5	11.5%	27.40	3.87	5.58
2.	Triglyceride	131.91	117.74	10.8%	33.23	4.699	3.021
3.	LDL	108.9	102.8	5.60%	40.71	5.75	1.06
4.	HDL	50.94	42.94	15.70%	25.25	3.57	2.24
5.	VLDL	29.84	31.34	5.02%	14.15	2.001	0.750

(BT- before trial, AT – after trial)

Mean score of serum cholesterol decreased up to 11.5%. It was statistically highly significant ($P < 0.001$) at the end of the trial. There was statistically significant decrease in Serum Triglyceride (10.8%), HDL level(15.7%) and Serum LDL level(5.60%). Only the one parameter VLDL increase (5.02%) during the trial. Which is statistically insignificant with the ' t ' value of 0.75 ($P > .05$).

CONCLUSION

The trial drug “Ashwagandhadilehya” is significantly effective in the management of age related problems. No adverse events were observed during the complete trial and after one month follow up. Therefore the trial drug Ashwagandhadilehya is safe and effective Rasayana drug when taken 10 gm orally per day in two divided doses with lukewarm milk.

REFERENCES

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