Research Article

A RANDOMISED DOUBLE-BLIND CLINICAL STUDY TO EVALUATE AND COMPARE THE EFFECTS OF *VRIDDADARU RASAYANA* WITH *BHARGAVAPROKTA RASAYANA* ON AGEING IN APPARENTLY HEALTHY ELDERLY SUBJECTS

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ABSTRACT

According to estimation, India currently has 6.7% over 65 years of age, which is expected to increase to 20% by the year 2050. As growing old is a part of the life cycle, the effect of time is bound to happen and is unavoidable. The *Kalajajara* is a *Swabhavika vyadhi*, wherein, it is clearly mentioned that *Swabhava balapravritta vyadhis* being *Yapya,* can be managed through *Bhojana, Paana*, and *Rasayana. Vriddadaru Rasayana* is one such *Rasayana* mentioned in *Gadanigraha* especially for the elderly to promote healthy ageing and helping to prevent old age problems. **Aims and objectives:** To assess the effect of *Vriddadaru Rasayana* in improving the general body health and quality of life in the apparently healthy elderly subjects. **Methodology:** A Randomized double blind clinical study where 20 healthy elderly subjects were administered with *Vriddadaru Rasayana* for a period of 12 weeks. **Observations and Results:** *Vriddadaru rasayana* showed improvement in Ayurvedic parameters like *Twakparushata, Slataasti, Slata sandhi, Utasahahani* and *Parakramahani* but when compared with regard to objective parameters *Vriddadaru rasayana* showed significant values in DHEAS levels and 6MWT. **Conclusion:** *Vriddadaru* does *Vatashamana,* balancing the *Doshas,* increasing the *Utsaha* and *Parakrama* and helps in improving the *Agni* thus helping in *Dhatuposhana* in the elderly.

KEYWORDS: *Jara*, Ageing, *Vriddadaru Rasayana, Bhargavaprokta Rasayana.*

INTRODUCTION

Ageing is a physiological process that starts from birth, continues throughout life and ends with death. This process of ageing is assessed by comparing biological age with chronological age. If biological age corresponds to chronological age, the ageing process is normal. If biological age lags behind chronological age, the ageing is delayed. If biological age has advanced ahead of chronological age, the ageing is described as precocious or premature.

According to estimation, India currently has 757 million persons over 65 years of age– coming to around 6.7% of the population– a gigantic leap from 3.4% in 1988, which is expected to increase to 20% by the year 2050. Elderly people often have limited regenerative abilities and are more susceptible to diseases. Increasing life span and poor health care add to the degree of disability among the elderly. Therefore, the care of elderly is mandatory.

In Ayurveda ageing is defined as *'Jara'. Jara* word derived from the root word *"Jrushvayohanau"* explained as *"Vayahkritaslathamamsadiavastha"* meaning loosening of muscle and other tissues under the influence of ageing.[1] According the *Sushruta Samhita, Vaya* (age) has been divided into three parts viz. *Balyavastha* (young age 0-16 yrs), *Madhyamavastha* (middle age 16-70 yrs) and *Jirnavastha* (old age >70 yrs). After 70 years there will be progressive diminution of *Dhatu,* strength of sense organs, vigor, masculinity, bravery, power of understanding, retaining and memorizing, speech and analyzing facts[2]. Thus, the *Vriddhavastha* or *Jirnavastha* is the last phase of life and is represented by the decay or degeneration of the body. *Sushrut acharya* has mentioned *'Jara'* (ageing) under *'Swabhava balapravritta vyadhi'* which is of two types viz. *Kalaja (Parirakshanakrita),* appearing at the proper time even after proper protection and *Akalaja (Aparirakshanakrita),* appearing before the proper time due to improper care and prevention. [3] *Jara* is an inescapable part of life, *Jara* occurring timely is unavoidable and irreversible. Whereas it can be delayed by maintaining the health of the elderly which can be achieved by *Rasayana*[4] which has been justified by *Chakrapani* with an example of *Chyavanamuni* who regained his youthfulness by the

consumption of *Chyavanaprasha rasayana (Bhargava prokta rasayana)*[5].

    Rasayana therapy is one such unique dedicated stream of Ayurveda, which includes immune protective and promotive, anti-degenerative and rejuvenated health care. It is known for its preventive action on ageing and improving the quality of life of healthy as well as diseased[6]. In order to obtain best results of *Rasayana* therapy it has been told to administer to a person who has self-control and has undergone proper *Shodhana* therapy. It has been clarified that, as the *Baala* and *Vridda* cannot tolerate the *Samshodhana* therapy, it is not advised to give *Shodhana* to them. The people who are fit for *Shodhana* are also eligible for *Rasayana* therapy [7]. Administration of *Rasayana* is highlighted during *Madhyavayas. Rasayana* administration during *Madhyavayas* is justifiable to control the damage and postponing the occurrence of *Jaraavastha*[8]. *Vriddadaru Rasayana* is one such *Rasayana* preparation mentioned in *Gadanigraha* for elderly individuals[9].

    Thus a clinical research study was planned to assess the *Rasayana* effect of the *Vriddadaru Rasayana* in healthy elderly subjects and to compare the effects of *Vriddadaru Rasayana* with *Bhargavaprokta Rasayana* as control group.

OBJECTIVES OF THE STUDY

1. To assess the effect of *Vriddadaru Rasayana* in improving the general body health and quality of life in the apparently healthy elderly subjects.
2. To compare the effects of *Vriddadaru Rasayana* with *Bhargavaprokta Rasayana*in improving the general body health and quality of life in the apparently healthy elderly subjects.

MATERIALS AND METHODS

    The drug compound *Vriddadaru* was procured from SDM pharmacy, Udupi. In this preparation the *Vriddadrumoola* has been dried under sunlight and powdered and mixed with *Grita* (ghee) and kept in a *Gritaliptapaatra* in *Dhanyarashi* for 1 *Paksha* (15 days). After 15 days obtained final product (*Avaleha*) can be consumed with milk as *Anupana.* The *Avaleha* was administered to patients of study group.

Subjects and Methods

    A total of 56 elderly volunteers were screened for the present study and amongst which 40 apparently healthy elderly individuals who were fulfilling the inclusion criteria were selected irrespective of their sex, caste, religion and socio-economic status after obtaining the informed written consent. Subjects were randomized to group study and control group, 20 in each group by Simple

Random Sampling Method. The subjects underwent routine examination including vital parameters and complete details were collected. The individuals were assessed before and after the intervention.

Criteria for Selection of Volunteers

Inclusion criteria

1. Apparently Healthy Male/Female volunteers of age between 60 and 75 years.
2. Willing to participate for 12 weeks and come for follow up after 4 weeks.

Exclusion criteria

1. Patient with systemic illness like uncontrolled hypertension, uncontrolled diabetes, ischemic heart disease, chronic obstructive pulmonary disease and other chronic diseases etc.
2. Patients who have completed participation in any other clinical trial during the past six months.

Sample Size Estimation

    The sample size was calculated using a standard formula for sample size estimation, with a power of 80% and level of confidence of 5%. Based on which, the number of samples required for each group was 19.84. Thus total sample taken was 40 with 20 subjects in each group.

Study Design

➢ Study Type: Interventional
➢ Allocation: Randomized
➢ Purpose: Prevention
➢ Blinding: Double Blind
➢ Timing: Prospective
➢ Control:*Bhargavaprokta Rasayana* (active control)
➢ Number of Groups: Two

Dose Fixation

    Based on a previous study conducted on the control drug *Bhargavaprokta Rasayana* on clinical efficacy and safety in apparently healthy elderly subjects, where in the dose given was 12gm orally twice daily for 12 weeks with milk as *Anupana*[10].

Intervention

Group A: *Vriddadaru Rasayana* (Intervention Group): 12gm administered orally twice daily on empty stomach in the form of *Avaleha* with milk .

Group B: *Bhargavaprokta Rasayana* (Control Group): 12 gm administered orally twice daily on empty stomach in the form of *Avaleha* with milk.

Duration of the study: 12 weeks after Randomization and drug administration. Subjects were reviewed on 0th, 30th, 60th and 84th day.

Follow up: 4 weeks after the completion of the study.

METHODS OF ASSESSMENT

The assessment of the study was done based on the subjective and objective parameters.

Subjective Parameters

A. The beneficial effects of *Rasayana* were evaluated in terms of changes in Ayurvedic parameters in terms of *Jaralakshanas* explained in the literature. The following signs and symptoms were graded for assessment. These were assessed before the administration of study drug at baseline and at every follow up.

B. **WHO-QOL-OLD[11]** Questionnaire assessment– they were assessed as FACETs once before administration of study and once after administration of study drug.

C. **6-minute walk test[12]-** once before and once after administration of drug.

Ayurvedic Parameters

1. *Twakparushata* **(Dryness of Skin)**
   Grade 0 - No dryness
   Grade 1 - Scratches can be made on the skin
   Grade 2 - Skin looks dry but not cracked
   Grade 3 - Skin looks dry with cracks

2. *Slathamamsa* **(Decreased Muscle Bulk)**
   Grade 0 - No muscle wasting
   Grade 1 - Either upper or lower limb muscle wasting
   Grade 2 - Both upper and lower limb muscle wasting
   Grade 3 - Generalized muscle wasting

3. *Slathaasthi* **(Bone Weakness)**
   Grade 0 - No bony pain
   Grade 1 - Occasional bony pain on pressure
   Grade 2 - Often feel discomfort and bony pain during light exertion
   Grade 3 - Dull aching pain even during rest

4. *Slatha sandhi* **(Flaccid Joint)**
   Grade 0 - No pain and sound in the joint
   Grade 1 - Occasional pain & crackling sounds in the joints
   Grade 2 - Often feels pain & crackling sounds in the joints
   Grade 3 – Always feel pain & crackling sounds in the joints

5. *Kayasyaavanamanam* **(Bending of the Body)**
   Grade 0 - No bending of the body
   Grade 1 - Mild bending of the body
   Grade 2 - Moderate bending of the body
   Grade 3 – Severe bending of the body

6. *Vepathu* **(tremors)**
   Grade 0 - No tremors
   Grade 1 - Occasional tremors
   Grade 2 - Often tremors
   Grade 3 – Always tremors

7. *Khalitya* **(Falling of Hair)**
   Grade 0 - No hair falling
   Grade 1 - Hair falling once in the morning while combing

Grade 2 - Hair falling during every time combing
Grade 3 – Visible baldness

8. *Vali* **(Wrinkling)**
   Grade 0 - No wrinkling
   Grade 1 - After skin raising, wrinkle subsides early
   Grade 2 - After skin raising, wrinkle persist for longer time
   Grade 3 – Wrinkle visible even without raising the skin

9. *Palitya* **(Graying of Hair)**
   Grade 0 - No graying of hairs
   Grade 1 - Very few gray hairs
   Grade 2 - Partial graying of hairs
   Grade 3 – Sufficient graying of hairs

10. *Kasa* **(Cough)**
    Grade 0 - No cough
    Grade 1 - Occasional cough
    Grade 2 - Recurrent cough
    Grade 3 - Always cough

11. *Shwasa* **(Short Breath)**
    Grade 0- No breathlessness
    Grade 1- Occasional breathlessness
    Grade 2- Often breathlessness on exertion
    Grade 3- Breathlessness even without exertion

12. *Dhatukshaya* **(Loss of Tissues)**
    Grade 0- Absence of *Dhatukshaya* symptoms
    Grade 1- Mild presence of *Dhatukshaya* symptoms
    Grade 2- Moderate presence of *Dhatukshaya* symptoms
    Grade 3- Severe presence of *Dhatukshaya* symptoms

13. *Grahana* **(Loss of Tissues)**
    Grade 0- No deterioration in grasping power
    Grade 1- Occasionally fails to grasp the subject
    Grade 2- Often fails to grasp the subject
    Grade 3- Always fails to grasp the subject

14. *Dharana* **(Retention Power)**
    Grade 0- No deterioration in retention power
    Grade 1- Occasionally fails to retain/hold up the Subject
    Grade 2- Often fails to retain/hold up the subject
    Grade 3- Always fails to retain/hold up the Subject

15. *Smarana* **(Memory Power)**
    Grade 0- No deterioration in retention power
    Grade 1- Occasionally fails to retain/hold up the Subject
    Grade 2- Often fails to retain/hold up the subject
    Grade 3- Always fails to retain/hold up the Subject

16. *Vachana* **(Speech)**
    Grade 0- No deterioration in speech
    Grade 1- Occasionally feels problem in speaking
    Grade 2- Often feels problem in speaking
    Grade 3- Always feels problem in speaking

17. *Vijnana* **(Knowledge)**
   Grade 0- Normal functioning in routine
   Grade 1- Gradual hampered performance in functions
   Grade 2- Often feels problem in speaking
   Grade 3- Always feels problem in speaking
18. *Utsahahani* **(Decreased Enthusiasm)**
   Grade 0- No decrease in enthusiasm
   Grade 1- Occasionally feels decrease in enthusiasm
   Grade 2- Often feels decrease in enthusiasm
   Grade 3- Always feels decrease in enthusiasm
19. *Parakramahani* **(Decreased Physical Strength)**
   Grade 0- No decrease in physical strength
   Grade 1- Occasionally feels decrease in physical Strength
   Grade 2- Often feels decrease in physical strength
   Grade 3- Always feels decrease in physical strength
20. *Prabhahani/Chhavihrasa* **(Changes in Complexion)**
   Grade 0- No changes in complexion
   Grade 1- Mild changes in complexion
   Grade 2- Moderate changes in complexion
   Grade 3- Severe changes in complexion
21. *Drishti hrasa* **(Diminished Vision)**
   Grade 0- No diminished vision
   Grade 1- Mild loss of range of visual accommodation
   Grade 2- Moderate loss of range of visual accommodation
   Grade 3- Severe loss of range of visual accommodation
22. *Karmendriyahani* **(Decreased Locomotor Activities)**
   Grade 0- No decrease in locomotor activities
   Grade 1- Mild decrease in locomotor activities
   Grade 2- Moderate decrease in locomotor activities
   Grade 3- Severe decrease in locomotor activities

23. *Buddhihani* **(Deterioration in Wisdom)**
   Grade 0- No deterioration in wisdom
   Grade 1- Mild deterioration in judgment based on knowledge and experience
   Grade 2- Moderate deterioration in judgment based on knowledge & experience
   Grade 3- Severe deterioration in judgment based on knowledge & experience

Objective Parameters
1. CBC (Complete Blood Count) with ESR.
2. Hs - CRP (High sensitivity C-reactive protein).
3. Inflammatory markers – TNF-Alpha, INF-Gamma.
4. DHEAS hormonal assay.

OBSERVATIONS

In the present study overall majority (57.5%) were females. In group A majority 14 (70%) were females, but in group B majority were males 11 (55%). Majority of the individuals (65%) included belonged to the age group 60-65years, with 12 (60%) in group A and 14 (70%) in group B. All subjects were married and majority belonged to Hindu religion (97.5%).

In the present study maximum number of individuals belonged to middle class (50%) and around 52.5% of subjects having completed their primary education. As majority were females, most of them were home makers (55 %), with another 25% presently working and 20% retired employees. All the subjects were apparently healthy with good appetite with regular bowel and bladder habits and more than 60% of them having a sound sleep at night.

Demographic variables like height, weight, BMI and healthy vital parameters like Blood Pressure (BP)- both systolic (SBP) and diastolic (DBP), Heart Rate (HR), Respiratory Rate (RR) were captured before administration of study drug and were comparable among both groups as shown below in table no.1.

Table 1: Mean, Maximum (M) and minimum (m) value of all for the variables– Height, Weight, BMI, BP, Pulse Rate, and Respiratory Rate

Variables	Group A				Group B			
	MEAN	m	M	SD	MEAN	m	M	SD
Height (cm)	155	142	169	6.14	163.72	144	180	10.20
Weight (Kg)	58.91	37	82.8	12.48	62.32	51	75	7.41
BMI (Kg/m2)	24.3	18.10	32.3	4.10	23.37	16.6	27.5	2.98
SBP (mm Hg)	137	120	160	12.60	137	110	160	14.17
DBP (mm Hg)	84	70	90	5.98	86	80	100	5.98
Pulse Rate (per min)	81.2	68	90	4.17	76.2	50	94	9.01
Resp. Rate (per min)	19.3	18	22	1.62	19.15	18	22	1.49

RESULTS

Both groups showed improvements in subjective and objective parameters. When compared, Group A (*Vriddadaru Rasayana*) shows better improvements than Group B (*Bhargavaprokta Rasayana*) in some of the parameters like;

- Subjective parameters –like *Twakparushata, Slata-asti, Slata-sandhi, Utasaha-hani* and *Parakrama-hani* (Table no.2 and Table no.3)
- WHOQOL-OLD module– WHO Facet 2 and Facet 5 (Table no.4 and Table no.5).
- Objective parameters– Like High sensitivity C- Reactive Protein (Hs-CRP), TNF Alpha, INF Gamma and 6 minute walk test (table no. 6, 7, 8 and 9)**.**

Table 2: Effect of *Vriddadaru Rasayana* on *Jara Lakshanas*

Wilcoxon Signed Rank Test						
Subjective Parameter	**Z value**		**P value**		**Inference**	
	BT-AT	**BT-FU**	**BT-AT**	**BT-FU**	**BT-AT**	**BT-FU**
Twakparushata	-3.000	-3.000	0.003	0.003	**S**	**S**
Slatamamsa	0	0	1.000	1.000	NS	NS
Slataasthi	-2.828	-2.828	0.005	0.005	**S**	**S**
Slata sandhi	-3.162	-3.162	0.002	0.002	**S**	**S**
Kayasyaavanamanam	0	0	1.000	1.000	NS	NS
Vepatu	0	0	1.000	1.000	NS	NS
Khalitya	0	0	1.000	1.000	NS	NS
Vali	0	0	1.000	1.000	NS	NS
Palitya	0	0	1.000	1.000	NS	NS
Kasa	-2.449	-2.449	0.014	0.014	**S**	**S**
Shwasa	0	0	1.000	1.000	NS	NS
Dhatukshaya	0	0	1.000	1.000	NS	NS
Grahana	0	0	1.000	1.000	NS	NS
Dharana	0	0	1.000	1.000	NS	NS
Smarana	-1.414	-1.414	0.157	0.157	NS	NS
Vachana	0	0	1.000	1.000	NS	NS
Vijnana	0	0	1.000	1.000	NS	NS
Utsahahani	-3.606	-3.606	0.000	0.000	**S**	**S**
Parakramahani	-3.742	-3.742	0.000	0.000	**S**	**S**
Prabhahani	0	0	1.000	1.000	NS	NS
Drishtihrasa	0	0	1.000	1.000	NS	NS
Karmendriyahani	0	0	1.000	1.000	NS	NS
Buddhihani	0	0	1.000	1.000	NS	NS

Table 3: Comparison of effects of *Vriddadaru Rasayana* with *Bhargavaprokta Rasayana* on *Jara Lakshanas*

Mann Whitney U test						
Subjective Parameters		**Mean rank**		**Z value**	**P value**	**Inference**
		Group A	**Group B**			
Twakparushata	BT-AT	20	21	-0.316	0.752	NS
	BT-FU	20	21	-0.316	0.752	NS
Slatamamsa	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Slataasthi	BT-AT	18.7	22.3	-1.171	0.242	NS
	BT-FU	18.7	22.3	-1.171	0.242	NS

Slata sandhi	BT-AT	18	23	-1.612	0.107	NS
	BT-FU	18	23	-1.612	0.107	NS
Kayasyaavanamanam	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Vepatu	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Khalitya	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Vali	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Palitya	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Kasa	BT-AT	21	20	-0.333	0.739	NS
	BT-FU	21	20	-0.333	0.739	NS
Shwasa	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Dhatukshaya	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Grahana	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Dharana	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Smarana	BT-AT	20	21	-0.593	0.553	NS
	BT-FU	20	21	-0.593	0.553	NS
Vachana	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Vijnana	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Utsahahani	BT-AT	15.5	25.5	-3.187	0.001	S
	BT-FU	15.5	25.5	-3.187	0.001	S
Parakramahani	BT-AT	15.5	25.5	-3.187	0.001	S
	BT-FU	15.5	25.5	-3.187	0.001	S
Prabhahani	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Drishtihrasa	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Karmendriyahani	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS
Buddhihani	BT-AT	20.5	20.5	0.000	1.00	NS
	BT-FU	20.5	20.5	0.000	1.00	NS

Table 4: Effect of *Vriddadaru Rasayana* on WHO QOL-OLD FACET scores

	Data	Paired t test						% of change
		Mean	±SD	±SEM	Diff	t	P	
FACET I	BT	15.65	1.89	0.42	0	-	-	0
	AT	15.65						
	BT	15.65	1.89	0.42	0	-	-	0

	FU	15.65							
FACET II	BT	13.35	1.72	0.38	0	-	-		0
	AT	13.35							
	BT	13.35	1.72	0.38	0	-	-		0
	FU	13.35							
FACET III	BT	13.15	1.69	0.37	0	-	-		0
	AT	13.15							
	BT	13.15	1.69	0.37	0	-	-		0
	FU	13.15							
FACET IV	BT	11.80	2.94	0.65	0	-	-		0
	AT	11.80							
	BT	11.80	2.94	0.65	0	-	-		0
	FU	11.80							
FACET V	BT	15.55	2.70	0.60	0	-	-		0
	AT	15.55							
	BT	15.55	2.70	0.60	0	-	-		0
	FU	15.55							
FACET VI	BT	14.45	1.87	0.41	0	-	-		0
	AT	14.45							
	BT	14.45	1.87	0.41	0	-	-		0
	FU	14.45							

Table 5: Comparison of effects of *Vriddadaru Rasayana* and *Bhargavaprokta Rasayana* on WHO QOL-OLD FACET scores

	Group	Data	Unpaired t test			Between Gp	
			±SD	±SEM	Diff	t	P
FACET I	A	BT-AT	0	0	0	-	-
	B		0	0	0		
	A	BT-FU	0	0	0	0.80	0.42
	B		0.55	0.12	0.1		
FACET II	A	BT-AT	0	0	0	1	0.33
	B		0.44	0.1	-0.1		
	A	BT-FU	0	0	0	1	0.33
	B		0.44	0.1	-0.1		
FACET III	A	BT-AT	0	0	0	-	-
	B		0	0	0		
	A	BT-FU	0	0	0	-	-
	B		0	0	0		
FACET IV	A	BT-AT	0	0	0	1	0.33
	B		0.89	0.2	0.2		
	A	BT-FU	0	0	0	1	0.33
	B		0.89	0.2	0.2		
FACET V	A	BT-AT	2.70	0.60	0	1.45	0.16
	B		2.70	0.60	0		
	A	BT-FU	2.32	0.51	-0.3	1.45	0.16
	B		2.32	0.51	-0.3		
FACET VI	A	BT-AT	1.87	0.41	0	-	-
	B		1.87	0.41	0		

	A	BT-FU	2.59	0.58	0	-	-		
	B		2.59	0.58	0				

Table 6: Effects of *Vriddadaru Rasayana* and *Bhargavaprokta Rasayana* on objective parameters

	Group	Data	Unpaired t test				Within Group		Comparison b/n Groups	
			Mean	±SD	±SEM	Diff	t	P	t	P
Hb (gm%)	A	BT	13.25	1.30	0.29	-0.38	1.59	0.12	-1.73	0.091
		AT	12.87	1.45	0.32					
	B	BT	13.24	1.36	0.30	0.14	-0.76	0.45		
		AT	13.38	1.32	0.29					
ESR (mm/hr)	A	BT	30	16.6	3.71	1.3	-0.27	0.78	0.708	0.486
		AT	31.3	18.9	4.24					
	B	BT	28.5	9.94	2.22	-2.3	1.36	0.18		
		AT	26.2	10.3	2.31					
TNFα (pg/ml)	A	BT	19.26	13.3	2.98	-1.54	1.69	0.10	0.376	0.709
		AT	17.72	11.7	2.62					
	B	BT	45.46	81.6	18.2	-2.12	1.72	0.10		
		AT	43.34	79.8	17.8					
INFγ (ng/ml)	A	BT	6.34	3.19	0.71	2.24	-0.94	0.35	0.60	0.551
		AT	8.58	11.0	2.46					
	B	BT	6.00	4.78	1.07	0.75	-1.13	0.27		
		AT	6.75	7.54	1.68					
DHEAS (mcg/dl)	A	BT	1.02	1.08	0.24	-0.22	2.44	0.02	-1.44	0.158
		AT	0.80	0.73	0.16					
	B	BT	1.11	0.72	0.16	-0.03	0.28	0.77		
		AT	1.08	0.73	0.16					

Table 7: Effects of *Vriddadaru Rasayana* on Hs-CRP

Wilcoxon Signed Rank Test			
Hs-CRP	Z value	P value	Inference
BT-AT	-1.00	0.317	NS

Table 8: Comparison of effects of *Vriddadaru Rasayana* and *Bhargavaprokta Rasayana* on Hs-CRP

Mann Whitney U test					
Objective parameter	Data	Mean Rank		Z value	P value
		Group A	Group B		
Hs-CRP	BT-AT	19.13	21.88	-1.125	0.261

Table 9: Comparison of effects of *Vriddadaru Rasayana* and *Bhargavaprokta Rasayana* on 6MWT

	Group	Data	Unpaired t test				Within Group		Between Group	
			Mean	±SD	±SEM	diff	t	P	t	P
6MWT	A	BT	333.0	41.1	9.20	34.5	-5.5	0	1.48	0.145
		AT	367.5							
	B	BT	336	45.2	10.1	21	-3.1	0.005		
		AT	357							

DISCUSSION

Rasayana chikitsa or rejuvenation therapy is one among the eight specialties of Ayurveda helps to promote and preserve health and longevity in the healthy and to cure diseases in sick population. *Rasayana* may not be always a drug therapy alone, but also includes various other aspects like food as *Nitya sevaniya dravya*, good conducts as *Sadvritta* and behaviour as *Achara Rasayana* and thereby they preserve positive health by influencing the

fundamental aspects of a body through *Dosha, Dhatu, Agni* and *Srotas.*

Drug Review and its Probable Mode of Action

In *Gadanigraha, Samanya Rasayanadhikara* and *Astangasangraha Rasayanadhikara*, we get a detailed description of the drug *Vriddadaru.* Due to its *Katu, Tikta, Kashaya rasa* and *Ushnaveerya* it does *Kapha-vatashamana.* And it is told that the person who consumes *Vriddadaru Rasayana* will become vigorous and active like a young adult. Further it is explained that *Bhagnasti* person will attain *Shlistasthi, Gadgadavaak* will have *Madhuravaak,* person having *Pangu* will walk properly*, Krusha* will become *Sthula* and *Hrisva* will become *Dheergha.*

According to *Sushrutha Samhita* there are two varieties of *Vriddadaru,* which are mentioned in *Gulmavishapahagana* along with the other drugs like *Trivrit, Danti, Kampillaka, Kramuka*, etc. Here there is mentioning of the word *Chagalantri* which is a synonym of *Vriddadaru,* whereas *Dalhana* comments it as *Vriddadarubedha.* But, there is no detail description of the 2 varieties of *Vriddadaru.*

The ingredient of *Vriddadaru Rasayana* is *Vriddadarumoola* which is said to have Kapha-*Vatashamaka* property. In *Vriddhavastha* as we have seen there will be predominancy of *Vatadosha*, so this Yoga may help in controlling *Vatadosha* and can bring it to normalcy. *Katu, Tikta* and *Kashaya rasa* has the property of enhancement of Agni and does the dilatation of *Srotus*. Due to this there will be improvement in digestion as well as absorption of *Ahara rasa*. Proper absorption of *Ahara rasa* in *Grahani* will promote the nourishment of all *Dhatu*. Since it has got *Ushnavirya* and *Madhuravipaka*, which leads to further enhancement of Agni, because of which the Rasa will form the *Uttarottaradhatu* properly and does *Dhatuposhana*. The *Laghu-Snigdhaguna* of *Vriddadaru* further does *Dhatu poshana* and helps to relieve the problem established because of depleted *Dhatu. Katu, Tikta* and *Kashaya* rasa of *Vriddadaru* in combination shows the quality of *Sandhanakara* as well as *Sthirikarana* of *Dhatu*.

Due to *Laghu- snigdhaguna, Vatahara* property there was reduction in *Twakparushata.* Due to *Tikta* and *Kashaya rasa* which shows the effect in the form of *Sthirikarana* (stabilizing) and *Sandhana karana* of the *Shareera*, *Dhatu* and *Asti,* the symptom of *Slataasthi* which is due to depletion of *Asthidhatu* was rectified. The improvement in *Slata sandhi* can be justified because of the *Laghu- snigdhaguna, Ushnaveerya, Deepana* action and *Vata-kaphahara* properties.

The improvement in *Smarana shakti* is may be because of *Katu rasa* and *Madhuravipaka. Katurasa* nourishes all the *Indriya* and does the

Vivarana of *Srotas* and maintain their patency and also it helps to attain the normalcy of *Manas* leading to the improvement in *Smaranashakti.* In elderly the *Smaranhani* can also be due to *Vataprakopa* which can be rectified by the *Madhuravipaka* as well as *Brihmana* property of *Vriddadaru.*

The *Katu-tikta-kashaya rasa, Laghu-snigdhaguna, Ushnaveerya, Deepana, Balya* and *Vata-kaphahara* properties of *Vriddadaru* will lead to improved *Utsaha* in the elderly. And, the quality of *Parakrama* is influenced by *Dhatu* as well as *Manas. Vriddadaru* by its *Rasayana* effect improves the quality of *Rasadidhatu* and shows the positive effect over *Manas* by its *Katu rasa*. Due to which there was improved strength in the subjects. Also, *Vriddadaru* has *Snigdhaguna, Balya* action and *Vata-kaphahara* property which helps to improves the *Parakrama*.

Argyreia speciosa (botanical name of *Vriddadaru*) was reported to stimulate both cellular and humoral immunity[13] and the alcoholic extract of the roots showed significant anti-inflammatory and analgesic activity[14]. Few of the studies also showed a significant result in learning, memory and cognition in mice.[15] So, as in old age there will be diminution of the immunity, inflammatory changes and diminution in cognitive function, memory, grasping, speech, wisdom, etc. Thus this drug may help in improvement of these functions in elderly.

Since the study was conducted in apparently healthy individuals, the health status was maintained even after the administration of the study drug. Thus there was no significant improvement seen in all the parameters and hence, it can be interpreted that the health status was not deteriorated.

With regard to the objective parameters, Hemoglobin can be low in elderly due to various reasons like low production, iron deficiency, Vit B12 deficiency thus the discrepancy in scores between Group A and Group B. These results could have been by chance rather than a finding of the study. Like Hb, there could be age and sex related variations in ESR and majority of our study subjects were female. However, both these results of Hb and ESR did not show significant difference between the groups.

With regard to bio-chemical parameters, both study drug and control drug has anti-inflammatory properties, this is shown as decrease in TNF Alpha and improvements in Hs-CRP scores in both groups (in subjects with positive Hs-CRP at baseline turned negative after study period). Though the study group showed improvement, it was not statistically significant.

As per literature, study drug has positive effects on both humoral immunity and cellular immunity and thus it shows improvement in INF

Gamma. And, in elderly as age progresses the DHEAS levels decline to about 10-20% of young individuals. Thus the decrease in DHEAS levels in study group may be because of age related decrease and may not be related to trial drug.

With regard to 6-Minute Walk Test, In Group A, there was 10.3% improvement at p=0, which is statistically highly significant. But in Group B there was 6.25% improvement at p=0.005, which is statistically significant. Thus, it can be stated that the trial drug helps in improving physical health of the individual by increasing their functional capacity due to its rejuvinative and aphrodisiac action as it is helpful in improving the *Utsaha* and *Parakrama*.

With regard to WHO QOL-OLD Module, FACET I comprised of the sensory abilities. Some of the subjects in the study had refractive errors majorly compared to other sensory disabilities and thus some improvement was seen in Group A compared to Group B, however it was not statistically significant. FACET II comprised of autonomy in old age, the ability to take their own decisions, do the activities on their own, here again the study group showed better scores, however it was not statistically significant. FACET III referred to achievements of the subjects in the past, opportunity to achieve the same in present, looking forward into their future, and FACET IV comprised of level of activity, quality of activity and their participation of activities of community respectively. Both these scores showed no significant difference between Group A and Group B. we feel our sample size was small and study period brief to have any significant results effect on these FACETS. FACET V comprised fear of death and FACET VI feeling of companionship respectively, most of our study subjects were married and having a lovely family, thus study showed no significant difference in these scores.

Thus *Vriddadaru Rasayana*, with regard to all above mentioned parameters, though did not show improvement, was not inferior to control drug and can be incorporated into routine usage as *Rasayana* in elderly.

CONCLUSION

Rasayana therapy serves both the aims of Ayurveda that is preserving the health of a healthy individual and curing the illness. *Rasayana* therapy helps to improve both qualitative and quantitative aspects of life. Due to its benefits such as achieving *Dheergayu,* improving *Smriti* and *Medha, Vayahsthapana* and *Jaravyadhinashana* it has been included under the eight major branches of Ayurveda. Though when compared to active control *Bhargavaprokta rasayana* no significant difference was found, *Vriddadaru rasayana* showed significant

improvements in Ayurvedic parameters like *Twakparushata, Slataasti, Slata sandhi, Smarana, Utsahahani, Parakramahani.* Also, there were improvements in objective parameters like DHEAS hormonal assay, Hs-CRP, TNFα and INFγ, 6MWT in *Vriddadaru* group*.* This can be justified as *Vriddadaru* does *Vatashamana,* balancing the *Doshas,* increasing the *Utsaha* and *Parakrama* and helps in improving the *Agni* thus helping in *Dhatuposhana* in the elderly.

Limitations and Scope for Future Research

Sample size of study was small. Future studies can be planned with larger sample size and with different combinations of *Rasayana*. Studies with subjects equally influenced by food, lifestyle and environment can be planned.

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