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, Sletaasti, Slata sandhi, Utsahahani 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 Dhoutposhana 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 “Vayakhritislathamamsadiavastha” meaning loosening of muscle and other tissues under the influence of ageing.[3] 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 Jinnavastha (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 jinnavastha 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]. Vridhadaru 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 Vridhadaru Rasayana in healthy elderly subjects and to compare the effects of Vridhadaru Rasayana with Bhargavaprokta Rasayana as control group.

OBJECTIVES OF THE STUDY
1. To assess the effect of Vridhadaru Rasayana in improving the general body health and quality of life in the apparently healthy elderly subjects.
2. To compare the effects of Vridhadaru Rasayana with Bhargavaprokta Rasayanaain improving the general body health and quality of life in the apparently healthy elderly subjects.

MATERIALS AND METHODS
The drug compound Vridhadaru was procured from SDM pharmacy, Udupi. In this preparation the Vridhadrumoola has been dried under sunlight and powdered with Grita (ghee) and kept in a Gritaliptaaputra 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: Vridhadaru 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 Jarakalakshanash 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. **Kayasyaavanamananam (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  |

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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, Utsaha-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).

| Subjective Parameter | Z value | P value | Inference |
|----------------------|---------|---------|-----------|
| Twakparushata        | BT-AT   | BT-FU   | BT-AT     | BT-FU     | 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         |

| Subjective Parameter | Z value | P value | Inference |
|----------------------|---------|---------|-----------|
| Kasyaavanamanam      | 0       | 0       | 1.000     | 1.000     | NS        | NS        |
| Vepatu               | 0       | 0       | 1.000     | 1.000     | NS        | NS        |
| Khaliya              | 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        |

Table 2: Effect of Vriddadaru Rasayana on Jara Lakshanas

| Subjective Parameter | Z value | P value | Inference |
|----------------------|---------|---------|-----------|
| 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        |
| Vijñana              | 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

| Subjective Parameters | Mean rank | Z value | P value | Inference |
|----------------------|-----------|---------|---------|-----------|
| Twakparushata        | BT-AT 20  | BT-FU 21 | -0.316  | 0.752     | NS        |
|                      | BT-AT 20  | BT-FU 21 | -0.316  | 0.752     | NS        |
| Slatamamsa           | BT-AT 20.5| BT-FU 20.5| 0.000   | 1.000     | NS        |
|                      | BT-AT 20.5| BT-FU 20.5| 0.000   | 1.000     | NS        |
| Slataasthi           | BT-AT 18.7| BT-FU 22.3| -1.171  | 0.242     | NS        |
|                      | BT-AT 18.7| BT-FU 22.3| -1.171  | 0.242     | NS        |
| Slata sandhi | BT-AT | 18 | 23 | -1.612 | 0.107 | NS |
| Kayasyaavanamanam | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Vepatu | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Khalitya | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Vali | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Palitya | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Kasa | BT-AT | 21 | 20 | -0.333 | 0.739 | NS |
| Shwasana | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Dhatukshaya | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Grahana | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Dharana | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Smaran | BT-AT | 20 | 21 | -0.593 | 0.53 | NS |
| Vachana | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Vijnana | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Utsahahanan | BT-AT | 15.5 | 25.5 | -3.187 | 0.001 | S |
| Parakramahanan | BT-AT | 15.5 | 25.5 | -3.187 | 0.001 | S |
| Prabhahanan | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Drishtihrasa | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Karmendriyahana | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |
| Budhahanan | BT-AT | 20.5 | 20.5 | 0.000 | 1.00 | NS |

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

| FACET I | BT | 15.65 | 1.89 | 0.42 | 0 | 0 |
| FACET I | AT | 15.65 | - | - | - | - |

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

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     | BT-AT | 0   | 0    | 0   | -  | -  |
| A     | BT-FU | 0   | 0    | 0   | 0.80 | 0.42 |
| B     | BT-FU | 0.55 | 0.12 | 0.1 | -  | -  |
| FACET II | |     |     |     |     |
| A     | BT-AT | 0   | 0    | 0   | 1   | 0.33 |
| B     | BT-AT | 0.44 | 0.1  | -0.1 | - | - |
| A     | BT-FU | 0   | 0    | 0   | 1   | 0.33 |
| B     | BT-FU | 0.44 | 0.1  | -0.1 | - | - |
| FACET III | |     |     |     |     |
| A     | BT-AT | 0   | 0    | 0   | -  | -  |
| B     | BT-AT | 0   | 0    | 0   | -  | -  |
| A     | BT-FU | 0   | 0    | 0   | -  | -  |
| B     | BT-FU | 0   | 0    | 0   | -  | -  |
| FACET IV | |     |     |     |     |
| A     | BT-AT | 0   | 0    | 0   | 1   | 0.33 |
| B     | BT-AT | 0.89 | 0.2  | 0.2 | -  | -  |
| A     | BT-FU | 0   | 0    | 0   | 1   | 0.33 |
| B     | BT-FU | 0.89 | 0.2  | 0.2 | -  | -  |
| FACET V | |     |     |     |     |
| A     | BT-AT | 2.70 | 0.60 | 0   | 1.45 | 0.16 |
| B     | BT-AT | 2.70 | 0.60 | 0   | -  | -  |
| A     | BT-FU | 2.32 | 0.51 | -0.3 | 1.45 | 0.16 |
| B     | BT-FU | 2.32 | 0.51 | -0.3 | -  | -  |
| FACET VI | |     |     |     |     |
| A     | BT-AT | 1.87 | 0.41 | 0   | -  | -  |
| B     | BT-AT | 1.87 | 0.41 | 0   | -  | -  |
### Table 6: Effects of Vriddadaru Rasayana and Bhargavapakra Rasayana on objective parameters

| Group | Data | 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 | 0 | 0 | 0 | 0 |
| | B | BT | 13.24 | 1.36 | 0.30 | 0.14 | -0.76 | 0.45 | 0 | 0 |
| | AT | 13.38 | 1.32 | 0.29 | 0 | 0 | 0 | 0 |
| 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 | 0 | 0 | 0 | 0 |
| | B | BT | 28.5 | 9.94 | 2.22 | -2.3 | 1.36 | 0.18 | 0 | 0 |
| | AT | 26.2 | 10.3 | 2.31 | 0 | 0 | 0 | 0 |
| 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 | 0 | 0 | 0 | 0 |
| | B | BT | 45.46 | 81.6 | 18.2 | -2.12 | 1.72 | 0.10 | 0 | 0 |
| | AT | 43.34 | 79.8 | 17.8 | 0 | 0 | 0 | 0 |
| 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 | 0 | 0 | 0 | 0 |
| | B | BT | 6.00 | 4.78 | 1.07 | 0.75 | -1.13 | 0.27 | 0 | 0 |
| | AT | 6.75 | 7.54 | 1.68 | 0 | 0 | 0 | 0 |
| 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 | 0 | 0 | 0 | 0 |
| | B | BT | 1.11 | 0.72 | 0.16 | -0.03 | 0.28 | 0.77 | 0 | 0 |
| | AT | 1.08 | 0.73 | 0.16 | 0 | 0 | 0 | 0 |

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

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

### Table 8: Comparison of effects of Vriddadaru Rasayana and Bhargavapakra Rasayana on Hs-CRP

| Objective parameter | Data | Mean Rank | Z value | P value |
|---------------------|------|-----------|---------|---------|
| Hs-CRP | BT-AT | 19.13 | 21.88 | -1.125 | 0.261 |

### Table 9: Comparison of effects of Vriddadaru Rasayana and Bhargavapakra Rasayana on 6MWT

| Group | Data | 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 | 41.1 | 9.20 | 34.5 | -5.5 | 0 | 1.48 | 0.145 |
| | B | BT | 336 | 45.2 | 10.1 | 21 | -3.1 | 0.005 | 0 | 0 |
| | AT | 357 | 45.2 | 10.1 | 21 | -3.1 | 0.005 | 0 | 0 |

### 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 conductas 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 Shisthasthi, Gadgadavaak will have Madhuravaak, person having Pangu will walk properly, Krusha will become Sthula and Hriswa will become Dheergha.

According to Sushrutha Samhita there are two varieties of Vriddadaru, which are mentioned in Gulnavishapahagana 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 Vriddadarumoolu 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 Srotas. 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 Vataprapoika 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 rejuvenative 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 Dheeragya, improving Smriti and Medha, Vayasthapana and Jaravyadhinashana it has been included under the eight major branches of Ayurveda. Though when compared to active control Bhargavaprotka rasayana no significant difference was found, Vriddadaru rasayana showed significant improvements in Ayurvedic parameters like Twakparushhata, 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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