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CLINICAL EFFICACY AND SAFETY OF BRAHMA RASAYANA IN APPARENTLY HEALTHY ELDERLY PERSONS: A PROSPECTIVE STUDY

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ABSTRACT

Background: Rasayana therapy is one of the branches of Ayurveda, which aims at promoting the excellence of Dhatu, improving inherent defence mechanisms in our body, and improving general health. **Aim:** To assess the clinical efficacy and safety of Brahma Rasayana in apparently healthy elderly persons. **Materials and methods:** The clinical study was undertaken at OPD basis at Muktainagar, Khandesh, Maharashtra. Fourty five apparently healthy elderly persons fulfilling the inclusion criteria were enrolled in the study. Brahma Rasayana was administered orally in the dose of 15 grams twice a day on empty stomach with lukewarm milk for a period of 12 weeks (84th day). Parameters, like hematological parameters, lipid profile, liver function tests, renal function tests, thyroid stimulating hormone (TSH), serum calcium, and serum vitamin D3 level, were assessed before and after the administration of therapy. To compare mean changes from baseline to the 84th day. **Results:** A statistically significant effect ($p < 0.0001$) was observed at the end of the 84th day, and chief complaints at the end of 12 weeks, compared with the baseline. Non-significant changes in blood parameters were obtained, proving the safety of the test drug. Also, the significant increase in the serum vitamin D3 level and decrease in the fasting blood sugar level were observed. Conclusion: Brahma Rasayana was found to be effective, safe, and tolerable in apparently healthy elderly volunteers.

KEYWORDS: Brahma Rasayana, Dhatu Poshana, Rasa Dhatu.

INTRODUCTION

The word Rasayana is defined as "Rasasya Ayanam Rasayanam."[1] Rasa means the absorbable end product of digestion or the nutrient obtained from food that gets assimilated

into the circulation model and spreads throughout the body, providing nourishment to the individual as a whole. Ayana means Marga,[2] i.e., the channels of circulation. Thus, the word Rasayana refers to providing essential nourishment and vital essence to all Dhatus in the body, thereby revitalizing and promoting their functional excellence.

Ayurveda conceives a unique concept of ojas, which is the quintessence of all the Dhatus and is responsible for the vital strength of the body and resistance against diseases, i.e., immunity.[3,4] Rasayana is believed to promote the process of Dhatu Poshana by Srotosodhana and Agni Deepana and enrich Ojas, leading to Vyadhikshamatva. The defense mechanism or immune mechanism present in our body allows us to survive in the potentially hostile world of infectious agents. Use of Rasayana enhances the immunity and reduces the susceptibility to diseases.

Rasayana therapy is one of the branches of Ashtanga Ayurveda. Rasayana therapy has been classified by Charaka into two groups: (a) Kutipraveshika Rasayana Vidhi (Rasayana therapy done indoors with a strict regimen) and (b) Vatatapika Rasayana Vidhi (Rasayana that can be done without resorting to a stringent regimen). According to the requirement of an individual, the Rasayana drugs are divided into three groups, viz. Kamya Rasayana (which is aimed at the promotion of normal health and often done with a specific purpose), Naimittika Rasayana (which is used for a short and specific period and also in disease treatment), and Ajasrika Rasayana (substances that can be used regularly for the improvement of health). Ayurveda has mentioned a set of behavioral and regimental modalities, such as the daily intake of Kshira (milk) and Ghrita (ghee), which promotes mental and social well-being of an individual, namely, Achara Rasayana which provides the effect of Rasayana without medication.

The concept of strengthening the inherent defence mechanism in our body can be done in a better way by means of Rasayana therapy. Brahma Rasayana is mentioned in the Abhayamalakeeya Rasayana Pada of Charaka Samhita, Chikitsa Sthana.[5] The effects of Brahma Rasayana is said to be many fold; like rejuvenation of the body, enhancing immunity, delaying the ageing process, augmenting vitality, and preventing the early onset of graying of hair and wrinkling of skin.

Benefits, such as the improvement of intellect, memory, and body glow, prevention of diseases, and slowing down of the ageing process leading to increased lifespan, are described

for Rasayana in Ayurveda classics.[6] Numerous medicines are described in Ayurveda classics as having Rasayana properties. The use of such medicines can help in improving the general health of the population and thus reducing the burden of diseases. Even though many of these medicines have been in use since centuries, scientific data on the clinical safety of these medicines are not available. Thus, the study aims to assess the safety and effectiveness of Brahma Rasayana in healthy elderly people, reducing the symptoms related to ageing and various other objective parameters by means of a clinical study.

MATERIALS AND METHODS

The study was a prospective open-label clinical trial, conducted at Muktainagar, Maharashtra on OPD basis.

A total of 45 participants were enrolled in the trial after obtaining the written informed consent.

Inclusion criteria

Apparently healthy individuals of either sex, with age ranging between 50 and 75 years, who had complaints of general weakness, but without involvement of any particular system and willing to provide informed consent.

Exclusion criteria

Patients with evidence of malignancy, suffering from major systemic illness necessitating long-term drug treatment (rheumatoid arthritis, psycho-neuro-endocrine disorders, etc.), who had a past history of atrial fibrillation, coronary artery disease (CAD), acute coronary syndrome, myocardial infarction, and stroke or severe arrhythmia in the last 6 months; symptomatic patients with clinical evidence of heart failure; patients with poorly controlled hypertension; and participants 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. Participants with concurrent serious hepatic disorder (defined as aspartate amino transferase (AST) and/or alanine amino transferase (ALT), total bilirubin, alkaline phosphatase (ALP) >2 times the upper normal limit) or renal disorders (defined as serum creatinine >1.2 mg/dL); participants with severe pulmonary dysfunction (uncontrolled bronchial asthma and/or chronic obstructive pulmonary disease [COPD]), inflammatory bowel disease (IBD), severe dementia, and severe infection(s); nonambulatory patients or any other conditions that would have jeopardized the study, prostate specific antigen (PSA) levels

> 4 ng/mL, alcoholics and/or drug abusers; patients suffering from diabetes mellitus; HIV positive subjects; participants with a history of hypersensitivity to the trial drug or any of its ingredients; and participants who had completed participation in any other clinical trial during the past six (6) months or any other condition which the investigator thought may jeopardize the study were excluded from the study.

Posology

Brahma Rasayana was administered as Vatatapika Rasayana Vidhi in a dose of 15 grams twice daily on empty stomach with lukewarm milk as Anupana for a period of 12 weeks orally. The drug Brahma Rasayana7 was procured from a good manufacturing practice (GMP)-certified Ayurvedic pharmaceutical industry, i.e., M/s Indian Medicines Pharmaceutical Corporation Limited (IMPCL), Mohan, Uttarakhand, and Standardized following the standards mentioned in the Ayurvedic Pharmacopeia of India (API).

Assessment criteria

On the day of enrolment, i.e., at baseline visit, personal identification, demographic profile, medical history, and general physical and systemic examination were done.

Assessment of chief complaints, such as dizziness, constipation, urge incontinence, muscle ache, joint pain, and stiffness in joints; and generalized symptoms, such as disturbed sleep, loss of appetite, fatigue, generalized weakness, and a generalized sense of ill-being by the visual analog scale (VAS) scores, was done at baseline and after treatment, i.e., on the 84th day visit.

Laboratory parameters, such as hemoglobin (Hb), total leukocyte count (TLC), absolute eosinophil count (AEC), erythrocyte sedimentation rate (ESR), lipid profile, liver function test (LFT), renal function test (RFT), C-reactive protein (CRP), thyroid stimulating hormone (TSH), serum vitamin D3 levels, and serum calcium levels, were assessed at baseline and after the treatment (84th day).

Subsequent visits were planned at intervals of 2 weeks [14th day (visit 2), 28th day (visit 3), 42nd day (visit 4), 56th day (visit 5), 70th day (visit 6), and 84th day (visit 7)]. Volunteers were assessed and given study medication at each subsequent visit till the 84th day.

Study procedure

At the study site, data of all the volunteers were recorded in predesigned case report forms (CRFs) and were also entered in the electronic formats (e-formats) designed in MS-Excel with many data validation checks to ensure correct data entry. The e-formats and Xerox of the CRFs along with the laboratory investigation reports of the participants.

Out of the total 45 volunteers enrolled in the study, 3 dropped out during the course of the study. The intention-to-treat analysis was done and the data of all those volunteers who have completed at least the 14th day visit were imputed by the last observation carried forward (LOCF) method. Volunteers who dropped out after the baseline visit were only excluded from the analysis. Hence, data of total 45 volunteers were used for statistical analysis.

Statistical analysis

The outcome measures were analyzed as mean changes in the response from baseline to the 84th day. A p value of <0.05 was considered to be significant.All statistical analysis were perfomed using the stastitical package for social science (SPSS) software.

OBSERVATIONS

Out of 180 volunteers who participated in the study, 70.0% were males while the remaining 30% were females. The majority of the volunteers were married (96.7%). About 86.1% were literate enough to read and write, and the remaining 13.9% were illiterate. As per the socioeconomic status of the volunteers, maximum, 84.4%, were from above the poverty line and the remaining were from below the poverty line. About 71% of the patients were from urban area and 93.9% belonged to the Hindu religion. Vegetarians (82.8%) were more in number than nonvegetarians. Addictions in the form of alcohol, smoking, and tobacco chewing were observed in a negligible number of people. About

Table shows residential status.

Sr.no.	Rural	%	Semiurban	%	Urban	%
1	33	18.3	18	10	129	71.7

Table showing gender status.

Sr.no.	Male	%	Female	%
1	126	70	54	30

Table showing marital status.

Sr.no.	Married	%	Unmarried	%	Widower	%
	174	96.7	3	1.7	3	1.7

Table showing educational status.

Sr.no.	Illiterate	%	Read and Write	%
1	25	13.9	155	86.1

Table showing socioeconomic status.

Sr.no.	Above poverty line	%	Below poverty line	%
1	152	84.4	28	15.6

Table showing Shareerik Prakriti.

Sr.no.	Shareerik Prakriti	(N)	%
1	Vataja	12	6.67
2	Pitaja	1	0.6
3	Vata-Pitaja	79	43.9
4	Vata-Kaphaja	9	5
5	Pitta-Kaphaja	78	43.33
6	Sannipataja	1	0.6

56.1% volunteers had normal sleep pattern and the remaining (43.9%) had disturbed sleep. About 70.6% volunteers had regular bowel habit and 76.1% had regular urine output (Table 1).

The level of stress varied in these individuals: a minimal level of stress was observed in 56.7%, moderate in 28.3%, and 15% had too much emotional stress.

Among the 180 volunteers, maximum (43.9%) were of Vata-Pittaja Prakriti, followed by 43.3% of Pitta-Kaphaja Prakriti. Maximum numbers of patients were having moderate physical parameters in terms of Samhanana, Pramana, etc.

RESULTS

Dizziness, constipation, urge incontinence, muscle ache, joint pain, stiffness in joints, disturbed sleep, loss of appetite, fatigue, generalized weakness, and a generalized sense of ill-being were the major subjective complaints that were observed in these participants. It was observed from the study that a change from baseline to the 84th day was statistically highly significant in the cases of dizziness, constipation, urge incontinence, muscle ache, joint pain, and joint stiffness ($p < 0.0001$). The effect of Brahma Rasayana on generalized symptoms,

such as disturbed sleep, loss of appetite, fatigue, generalized weakness, and a sense of ill-being, was also highly significant with a p value <0.0001.

After the end of the 84th day of study, it was observed that *Brahma Rasayana* has provided no significant effect on the laboratory investigations (TLC, Hb%, ESR, AEC, TSH,and serum calcium) of the apparently healthy elderlyvolunteers. There were statistically significant reduction in fasting blood sugar and also statistically significant rise in vitamin D3 values after the therapy.

After the end of the 84th day of study, it was observed that *Brahma Rasayana* has no significant effect on the lipid profile except very-low-density lipoprotein (VLDL). The significant increase was observed in the VLDL level,which is found to be within the physiological limits of apparently healthy volunteers recruited in the study.

The effects of *Brahma Rasayana* on safety parameters were assessed through the evaluation of the RFT, LFT, and CRP, at the baseline and after the end of the study, and it was observed that all the parameters were within the physiological limits during the entire trial period and also after the end of the trial with *p* value >0.05.

After the administration of therapy for a specific period of time, it was observed that Brahma Rasayana

Table shows effect of the therapy on chief complaints (n=180).

Sr.no.	Chief Complaints	Baseline	84th day
1	Dizziness	3.90 (08.30)	11.80 (18.10)
2	Constipation	2.69 (10.89)	10.50 (21.30)
3	Muscle Ache	2.61 (07.60)	15.30 (24.82)
4	Joint pain	5.40 (15.65)	17.75 (24.75)
5	Joint stiffness	5.61 (15.20)	13.63 (22.42)
6	Abnormal sleep	4.77 (10.21)	16.11 (21.54)
7	Loss of appetite	2.94(09.36)	07.05 (17.45)
8	Fatigue	5.72 (10.42)	20.17 (21.81)
9	Generalised weakness	7.18(26.49)	24.38 (34.16)
10	Sense of ill -being	-5.42 (07.65)	-24.72 (16.45)

Value are expressed as n(%),p value <0.0001

Table showing effect of therapy on the lipid profile (n=180).

Sr.no.	Parameter	Baseline	84th day
1	Serum cholesterol mg/dl)	187.16+-35.40	190.13+-34.68
2	Serum triglyceride (mg/dl)	129.96+_50.216	137.91+_75.815
3	Low density lipoprotein (LDL) (mg/dl)	120.98+_28.86	122.28+-29.40
4	High density lipoprotein (HDL) (mg/dl)	41.68+-10.86	41.52+_13.33
5	VLDL (mg/dl)	25.36+-8.78	27.46+-16.63

Data, means+_SD,p value of <0.05

Table showing the effect of the therapy on outcome parameters.

Sr.no.	Parameters	Baseline	84th day
1	Remote memory	5.35+_0.855	5.86+-0.474
2	Rescent memory	4.61+_0.655	4.94+-0.253
3	Mental balance	6.59+-1.687	7.91+-1.443
4	Attention and concentration	11.11+-3.88	12.58+-3.608
5	Delayed recall	7.96+_1.767	9.05+-1.183
6	Immediate recall	8.59+-2.62	4.82+-0.398
7	Verbal retention for similar pairs	4.41+-0.738	12.41+-2.842
8	Verbal retention for dissimilar pairs	9.71+-3.14	10.77+-2.315
9	Visual retention	10.28+-8.69	9.27+_0.966
10	Visual recognition	8.39+-1.669	88.16+-11.29

Data, Mean+SD, p value <0.001

provided a highly significant effect ($p < 0.0001$) recent memory, mental balance, attention and concentration, delayed recall, immediate recall, verbal retention for dissimilar pairs, visual retention, visual recognition. In the domain verbal retention for similar pairs, it was highly significant in the level of $p < 0.001$.

DISCUSSION

Rasayana 6 is a specialized treatment aimed at providing the overall improvement in an individual by prevention of ageing, promoting resistance against diseases, enhancing bodily strength, and improving mental faculties. The Rasayana drugs can act on the body by qualitative enhancement of the nutritional value of the Asthayee Rasa Dhatu, which in turn acts by improving Dhatu Poshana, e.g., Dugdha, Ghruta, Shatavaree, etc. Rasayana drugs have an important role in improving Agni Vyapara, i.e., proper digestion and metabolic transformation in the body, thereby regulating proper Dhatu Nirmana in the body (Chitraka, Bhallataka, etc., are few drugs capable of promoting Agni in Koshta and Dhatu levels). Certain drugs, such as Guggulu with Rasayana effect, have the ability to produce Srota Shodhana (cleansing the macro and macro channels in the body), which ultimately improves Dhatu Poshana Kriya.

Previous studies have also proven the efficacy of Brahma Rasayana for its antioxidant and tissue-regeneration capacity.10 Oral administration of Brahma Rasayana (50 mg/dose/animal) is found to have free oxygen radical-scavenging activity in in vitro and in vivo models.11 Another clinical study mentions an unexpected finding that the administration of Brahma Rasayana did not produce any significant increase in the total leukocyte or absolute counts of various WBCs or other hematological parameters, but there was a significant functional enhancement of lymphocytes in healthy volunteers. There was also a marginal increase in the serum granulocyte macrophage-colony stimulating factor (GM-CSF) in volunteers after ten days of Brahma Rasayana treatment when compared to the day prior to the start of Brahma Rasayana treatment.[12]

Brahma Rasayana rejuvenates the body, improves intelligence, boosts memory, and augments the immune mechanism. This is a very good tonic for enhancing youthfulness, luster, complexion, and efficiency of individuals. It is beneficial for promoting mental clarity and improved cognition whilst improving resilience to mentally demanding lifestyles. Its unique blend of herbs helps improving focus and concentration. It also increases sperm count and enhances libido.

It was noticed from the study that maximum volunteers were married and male, as the inclusion criteria included age ranging from 50 to 75 years. Maximum were literate and from urban area, which may be due to the fact that the study was conducted in an urban populated area where the provision for education is better. Maximum were having past occupational history of field work with physical labor. The majority of the participants were from above the poverty line, since most were from urban area where the livelihood is better. Maximum were from the Hindu community, since the study was conducted in areas where Hindu predominance in population is seen. The majority was observed to be nonvegetarians and was devoid of any addiction. The maximum number of volunteers had normal sleep pattern, regular bowel habit, and regular urine output, which may be due to the fact that apparently healthy volunteers were considered for the study. Quite a large number had average emotional stress, which may be due to the present lifestyle. Maximum were having average body built and were moderately nourished, which might be due to their regular physical labor. The majority were of Vata-Pitta Prakriti followed by Pitta-Kapha Prakriti and belonged to Mamsa Sara followed by Tvak Sara. All other criteria, such as Satva, Samhanana, Satmya, and Vyayama, were observed to be in the Madhyama category in majority of the participants.

In the present study, Brahma Rasayana showed a highly significant effect on most of the parameters viz. in subjective complaints like dizziness, constipation, urge incontinence, aching muscle, pain in joints, stiffness in joints, abnormal sleep, loss of appetite, fatigue, generalized weakness, and a sense of well-being, with p values <0.001. *Brahma Rasayana* can be believed to have antioxidant, nootropic, immune stimulant, and revitalizing properties. The generalized symptoms are reflection of functional deterioration of *Dhatu* secondary to free radical- and age-induced damage. *Brahma Rasayana* has promoted excellence of *Dhatus* by nourishing, replenishing, and regenerating them. Statistically significant reduction in fasting blood sugar and statistically significant rise in vitamin D3 values were also observed after the therapy. It was also observed that *Brahma Rasayana* improved the mental and psychosomatic attributes. No adverse events (AE) or adverse reactions (ADR) were noticed during the entire trial period. The values of LFT and RFT were within stipulated limits during the entire period.

CONCLUSION

Brahma Rasayana has provided highly significant improvement in somatic, psychological, and psychosomatic (subjective and objective) parameters including significant reduction in fasting blood sugar and statistically significant rise in vitamin D3 in apparently healthy elderly volunteers with no AE or ADR. Hence, it can be concluded that *Brahma Rasayana* can be acknowledged as an effective medication with *Dhatu Poshaka*, *Balya*, and *Ojo-vardhaka* properties, which is safe and effective to be used in people for revitalization, rejuvenation, and immune-stimulant activities.

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Conflict of interest: Authors are declaring that there is no conflict of interest.

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