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Research Article

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *AMALAKAVLEHA* AS *RASAYANA* IN HEALTHY INDIVIDUALS

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KEYWORDS: *Rasayana,* Rejuvenation, *Amalakavleha, Ojas.*

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ABSTRACT

Rasayana is one of the eight branches of classical Ayurveda, used for prevention of diseases and prolongation of a healthy life. *Rasayana* are rejuvenators, nutritional supplements, possess strong anti-oxidant activity and increases *Ojas*. *Rasayana* therapy enhances the qualities of *Rasa,* enriches it with nutrients so one can attain longevity, freedom from diseases, youthfulness, memory, intelligence; excellence in complexion, lustre and sense organs; development of healthy physique and rejuvenation of mind and body. Present study has been designed to evaluate the efficacy of *Amalakavleha* as *Rasayana* in healthy individuals. 45 individuals fulfilling the inclusion criteria were randomly selected and divided into two groups. In Group-I, 23 individuals were administered *Amalakavleha* and in Group-II, 22 individuals were given starch capsules as placebo for 8 weeks. Individuals were thoroughly assessed on various subjective and objective parameters during complete trial period. Group-I individuals showed statistically significant improvement on various treadmill test related parameters like exercise time, maximum work load, VO2 max and rate pressure product, whereas statistically insignificant changes in these parameters were observed in the individuals receiving placebo. In Group-I during TMT, exercise time increased by 8.15% and Group-II had a marginal increase of only 0.30%, rise of 8.97% observed in maximum work load attained in Group-I whereas Group-II individuals showed rise of 1.78%. In Group-I, Vo2 max had 4.10% rise as compared to Group-II, having negligible rise of 0.15%. RPP in Group-I increased by 6.75%, while in Group-II 0.21% change was noticed. These results prove the efficacy and safety of *Amalakavleha* as *Rasayana* in healthy individual's w.r.t. physical and mental health. No untoward effects of therapy were observed in study subjects during the entire trial period.

INTRODUCTION

Longevity is one of the primary instincts which are common among all living creatures. But there is no use of long life if a person is not healthy as quality of life is important for an individual. In today's competitive world, the erroneous life style is resulting in progressive decline in both physical and mental health. Sedentary life style super added with faulty eating patterns has led to marked reduction in health of individuals, which has resulted in a high incidence of various non communicable diseases. Ayurveda, an ancient science of life, developed through the ages, deals with physical, psychological as well as spiritual well being of an individual. It is not just the knowledge of medicine but the complete science of life.

"*Swasthasya Swasthya Rakshanam*"[1] means maintaining the health of a healthy person had been the prime aim of Ayurveda. In Ayurveda emphasis has been given to preventive aspect of health considering physical, mental, and social aspects rather treating a disease. To achieve this goal, daily regimen, seasonal regimen, code of conduct of diet

and social behaviour are mentioned in Ayurveda. *Rasayana*, which is one of the unique disciplines of Ayurveda, comprises a specialized use of herbs, herbo-mineral formulations, food articles, and lifestyle along with self-discipline and social etiquette to achieve the optimum state of tissues and systems of the body so that there is the least possibility of onset of disease. *Rasayana* is a specialized modality influencing the fundamental aspects of body viz. *Dhatu, Agni, Srotas, Ojas*. A person undergoing *Rasayana* or rejuvenation therapy attains longevity, memory, intellect, freedom from diseases, lustre of skin, excellent potency of body, good strength and good functioning of sense organs. Looking at the multifaceted approach of *Rasayana*, it can be said that *Rasayana* therapy incorporates various forms of health promotive activities in the form of diet, lifestyle, or medicines which target at achieving homeostasis *(Dhatu Samya)* thus retarding the process of aging, used to prevent diseases, promotion and prolongation of healthy life and not merely treating the disease.

The amalgamation of healthy living style and use of *Rasayana* can immensely help the mankind in preventing various diseases. *Rasayana* is having a replenishing effect on all the body tissues, organs and organ systems of the body.

AIMS AND OBJECTIVES

Primary Objective

To evaluate the efficacy of *Amalakavleha* as *Rasayana* in healthy individuals w.r.t general physical and mental fitness.

Secondary Objective

To assess the safety of *Amalakavleha* in healthy individuals when used as *Rasayana* w.r.t general physical and mental fitness.

Protocol of Research

1. **IEC Approval:** Approval of Institutional Ethical Committee was obtained before commencement of research work vide Letter No.- Ayu/IEC/2017/1137 dated 01/09/2018.
2. **CTRI Registration:** The study has also been registered in Clinical Trial Registry of India (CTRI) vide CTRI No.– CTRI/2019/09/021387 dated 23/09/2019, prospectively.
3. **Consent:** Written and informed consent of healthy volunteers was taken before inclusion in the trial.
4. **Case Record Proforma:** A detailed case record proforma was prepared before commencement of interventional drug and after completion of therapy.

MATERIALS AND METHODS

Selection of the Individuals

A total of 45 study subjects were selected from OPD/campus of R.G.G.P.G. Ayurvedic College and Hospital, Paprola, District Kangra (H.P.) irrespective of caste, sex, race and religion. A detailed history of study subjects was obtained, physical examination was conducted and relevant investigations were carried out before the enrolment and after the completion of trial period.

Inclusion Criteria

1. Healthy volunteers who were willing to undergo the clinical trial.
2. Individuals of either gender aged between 30–60 years.
3. Individuals who were able to participate for 8 weeks of duration.

Exclusion Criteria

1. Individuals who were not willing to undergo the treatment.
2. Individuals below 30 years and above 60 years of age.
3. History of hypersensitivity to the treatment drug or any of its ingredients.
4. Individuals who completed participation in any other clinical trial during the past six months.
5. Any other condition which the principal investigator thought may jeopardize the study.

Laboratory Investigations

Hb%, TLC, DLC, ESR, FBS, Blood urea, Serum creatinine, SGOT, SGPT, S.Lipid profile (S. Cholesterol, S. Triglycerides, HDL, LDL, VLDL), S.Proteins.

Grouping of the Study Subjects

Selected study subjects were randomly divided into following two groups.

Group I: In this group 23 study subjects were registered out of which two discontinued the treatment and 21 individuals completed the study. In this group study subjects were given *Amalakavleha* in dose of 10gm once in a day (in morning) with *Koshana Jala. Kohstha shuddhi* was done before commencement of *Rasayana* formulation i.e., *Amalakavleha* by administrating *Haritakayadi Yoga* in dose of 5g with lukewarm water at bed time for 3-7days according to *Koshtha*.

Group II: In this group 22 study subjects were given starch capsules (500mg once in a day) as placebo out of which two were drop out and only 20 individuals completed the study.

Apart from this, the individuals in both groups were asked to have a brisk walk of 30

minutes daily in the morning, *Pranayama* for 5 to10 minutes, low calorie, low sodium and low fat diet.

Duration of treatment: 8 Weeks

Route of administration: Oral

***Amalakavleha*[2]**

Trial Drugs

Interventional products were prepared at Government Charaka Ayurvedic Pharmacy, Paprola vide Licence No. HP-Ay-87.

Table1: Ingredients of *Amalakavleha*

Ingredients	Botanical Name	Family	Part used
Amalaki	*Emblica officinalis*	*Euphorbiaceae*	Pericarp
Pippali	*Piper longum*	*Piperaceae*	Fruit
Palash kshara	*Butea monosperma*	*Fabaceae*	–
Madhu (Honey)	–	–	–
Go-Ghrita (Ghee)	–	–	–
Sharkara	–	–	–

***Haritakayadi Yoga*[3]**

Table 2: Ingredients of *Haritakayadi Yoga*

Ingredients	Botanical Name	Family	Part used	Ratio
Haritaki	*Terminalia chebula*	*Combretaceae*	Pericarp	1
Amalaki	*Emblica officinalis*	*Euphorbiaceae*	Pericarp	1
Vacha	*Acorus calamus*	*Acoraceae*	Rhizome	1
Haridra	*Curcuma longa*	*Zingiberaceae*	Rhizome	1
Vishavbhaishaja	*Ziingiber officinale*	*Zingiberaceae*	Rhizome	1
Vidanga	*Embelia ribes*	*Myrsinaceae*	Fruit	1
Pippali	*Piper longum*	*Piperaceae*	Fruit	1
Saindhav lavana (Himalayan rock salt)	–	–	–	1
Guda (Jaggery)	–	–	–	1

Follow up and Assessment of the Study Subjects

A thorough assessment of the study subjects was done before commencement of the therapy (day zero) and at the 14th, 28th, 42nd and 56th day i.e. at the time of the completion of therapy. The effects of treatment were assessed on the basis of various subjective and objective parameters. Laboratory investigations were carried out before commencement and after completion of the treatment.

ASSESSMENT CRITERIA

Objective criteria

1. TMT related parameters like- Exercise time, Maximum work load attained in terms of Mets, VO2 max, Double product/RPP (Rate Pressure Product).
2. Body weight
3. BMI
4. Vital capacity
5. Foot thrust
6. Hand grip power

Subjective criteria

An elaborated Proforma for the assessment of general health was used for the assessment of subjective criteria (Individual questionnaire, Rotation–A, World Health organization evidence and information for policy, World Health Survey 2002). This questionnaire covered all those important aspects with which individuals often struggle like- Overall health, Self care, Sleep, Mobility, Cognition, Interpersonal activities etc. Subjective criteria of assessment were graded from 0 to 4.

Table 3: Grading of subjective Criteria

Sr. No.	Symptoms	Grade
1.	**Overall Health** **In general how would you rate your health today?**	
	Very good	G0
	Good	G1
	Moderate	G2
	Bad	G3
	Very Bad	G4
2.	**Overall in the last 30 days how much difficulty did you have with you work or household activities?**	
	None	G0
	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4
3.	**Mobility** **Overall in the last 30 days how much difficulty did you have in vigorous activities such as running 3km or cycling?**	
	None	G0
	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4
4.	**Self Care** **Overall in the last 30 days how much difficulty did you have with self care as washing or dressing yourself?**	
	None	G0
	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4
5.	**Overall in the last 30 days how much difficulty did you have in taking care of and maintaining your general appearance (grooming, looking neat and tidy etc.)?**	
	None	G0
	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4
6.	**Pain and Discomfort** **Overall in the last 30 days how much of bodily aches or pain did you have?**	
	None	G0
	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4

7.	**Overall in the last 30 days how much of bodily discomfort did you have?**	
	None	G0
	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4
8.	**Cognition** **Overall in the last 30 days how much difficulty did you have in concentrating or remembering things?**	
	None	G0
	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4
9.	**Overall in the last 30 days how much difficulty did you have in learning a new task?**	
	None	G0
	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4
10.	**Interpersonal Activities** **Overall in the last 30 days how much difficulty did you have in dealing with conflicts and tensions with others?**	
	None	G0
	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4
11.	**Sleep and Energy** **Overall in the last 30 days how much difficulty did you have with sleeping, such a falling asleep, waking up frequently during night or waking up to early in the morning?**	
	None	G0
	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4
12.	**Overall in the last 30 days how much difficulty did you have to not feeling rested and refreshed during the day?**	
	None	G0
	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4
13.	**Affect** **Overall in the last 30 days how much difficulty did you have with feeling sad, low or depressed?**	
	None	G0

	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4
14.	**Self Care** **Overall in the last 30 days how much difficulty did you have worry or anxiety?**	
	None	G0
	Mild	G1
	Moderate	G2
	Severe	G3
	Extreme	G4

OBSEVATIONS AND RESULTS

Out of 45 registered study subjects maximum were married (91%) male (64%) of age group between 41-50 yrs (44%) dwelling in rural area (78%) and Hindu (100%) by religion. 84% were literate and majority of them were involved in desk work (33%), taking vegetarian diet (53%), having reduced sleep (49%) and appetite (66.6%). 88% of study subjects had no addiction but rest of them were addicted either to smoking or alcohol. Majority of individuals had *Vata-Kaphaj Deha Prakriti* (42.22%) and *Rajsik Manas Prakriti* (44.44%). Majority were *Meda Sara* (35.55%) with *Madhyama Samhanana* (57.77%), *Satva* (51.11%), *Satmaya* (62.22%), *Pramana* (53.33%) and *Avara Aahara Shakti* (53.33%) and *Avara Vyayama Shakti* (42.22%).

Table 4: Assessment of Effects on TMT parameters

Variable	**Group**	**Mean Score**		**Percent Change**
		BT	**AT**	
Exercise time (In minutes)	Group-I	8.58	9.28	8.15%
	Group-II	6.56	6.54	0.30%
Max Work load (METS) (In term of Mets)	Group-I	10.19	11.11	8.97%
	Group-II	9.88	9.71	1.78%
VO2 Max (In ml/kg/ min)	Group-I	36.25	37.75	4.10%
	Group-II	34.41	34.47	0.15%
RPP (In mm Hg. Hz)	Group-I	24603.20	23045.63	6.33%
	Group-II	22152.57	22106.05	0.21%

Table 5: Statistical Analysis on Effects of Therapy on TMT Parameters

Variable	**Group**	**Mean Diff.**	**SD+**	**SE+**	**'t' value**	**'p' value**	**Intergroup p-value**
Exercise time (In minutes)	Group-I	0.70	1.78	0.49	4.452	0.009 (<0.01)	0.008
	Group-II	0.02	2.34	0.33	0.111	0.224 (>0.05)	
Max Work load (METS) (In term of Mets)	Group-I	0.92	1.19	0.27	3.437	0.003 (<0.01)	0.001
	Group-II	0.18	0.64	0.14	1.255	0.224 (>0.05)	
VO2 Max (In ml/kg/min)	Group-I	1.50	2.27	0.51	2.946	0.008 (<0.01)	0.007
	Group-II	0.06	0.48	0.10	0.519	0.610 (>0.05)	
RPP (In mm Hg. Hz)	Group-I	1557.57	2343.39	523.99	3.303	0.004 (<0.01)	0.004
	Group-II	46.52	1311.83	286.26	0.196	0.847 (>0.05)	

Table 6: Assessment Result on Other Objective Parameters

Variable	Group	Mean Score		Percent Change
		BT	AT	
Vital Capacity (In Litre)	Group-I	3.54	3.59	1.32%
	Group-II	3.35	3.36	0.29%
Foot Thrust (In Kg)	Group-I	65.60	66.90	1.98%
	Group-II	61.81	60.91	0.15%
Hand Grip Power (In mm of Hg)	Group-I	92.50	95.95	3.72%
	Group-II	94.60	93.75	0.90%
Body Weight (In Kg)	Group-I	65.80	65.81	0.01%
	Group-II	63.14	63.08	0.10%
BMI (In Kg/m2)	Group-I	22.36	22.37	0.02%
	Group-II	22.13	22.11	0.06%

Table 7: Statistical Analysis on Other Objective Parameters

Variable	Group	Mean Diff.	SD+	SE+	't' value	'p' value	Intergroup p-value
Vital Capacity (In Litre)	Group-I	0.05	0.18	0.05	3.425	0.007 (<0.01)	0.050
	Group-II	0.01	0.20	0.05	0.611	0.321 (>0.05)	
Foot Thrust (In Kg)	Group-I	1.30	1.59	0.36	3.650	0.002 (<0.01)	0.010
	Group-II	0.01	1.55	0.34	0.282	0.781 (>0.05)	
Hand Grip Power (In mm of Hg)	Group-I	3.450	3.83	0.86	4.027	0.001 (<0.001)	0.010
	Group-II	0.850	2.78	0.62	1.369	0.187 (>0.05)	
Body Weight (In Kg)	Group-I	0.01	0.45	0.10	0.049	0.961 (>0.05)	0.682
	Group-II	0.06	0.43	0.09	0.659	0.518 (>0.05)	
BMI (In Kg/m2)	Group-I	0.01	0.20	0.05	1.448	0.164 (>0.05)	0.180
	Group-II	0.02	0.17	0.04	0.396	0.697 (>0.05)	

Table 8: Assessment Result on Subjective Parameters

Variable	Group	Mean Score		Percent Change
		BT	AT	
Overall Health	Group-I	2.95	2.00	32.20%
	Group-II	2.91	2.81	3.09%
Mobility	Group-I	3.05	4.16	36.30%
	Group-II	1.95	2.06	5.60%
Self Care	Group-I	2.80	2.56	11.40%
	Group-II	2.95	2.81	4.80%
Cognition	Group-I	2.90	2.10	27.50%
	Group-II	3.14	3.00	4.45%
Interpersonal Activities	Group-I	3.00	1.90	36.60%
	Group-II	3.10	2.91	6.10%
Sleep	Group-I	2.95	1.90	35.50%
	Group-II	2.91	2.81	3.30%
Energy	Group-I	2.85	2.15	24.50%
	Group-II	2.76	2.81	1.70%

Table 9: Statistical analysis on subjective parameters

Variable	Group	Mean Diff.	SD+	SE+	't' value	'p' value	Intergroup p-value
Overall Health	Group-I	0.95	1.47	0.33	2.894	0.009 (<0.01)	0.010
	Group-II	0.10	0.30	0.07	1.451	0.162 (>0.05)	
Mobility	Group-I	1.11	1.71	0.38	2.871	0.010 (<0.01)	0.636
	Group-II	0.11	1.24	0.27	1.234	0.232 (>0.05)	
Self Care	Group-I	0.33	0.28	0.29	1.679	0.061 (>0.05)	0.684
	Group-II	0.14	0.36	0.08	1.826	0.083 (>0.05)	
Cognition	Group-I	0.80	1.32	0.29	2.707	0.014 (<0.01)	0.722
	Group-II	0.14	1.28	0.27	1.195	0.246 (>0.05)	
Interpersonal Activities	Group-I	1.10	1.45	0.32	3.399	0.003 (<0.01)	0.023
	Group-II	0.19	0.98	0.21	0.890	0.384 (>0.05)	
Sleep	Group-I	1.05	1.43	0.32	3.280	0.004 (<0.01)	0.005
	Group-II	0.10	0.30	0.07	1.451	0.162 (>0.05)	
Energy	Group-I	0.70	1.30	0.29	2.405	0.027 (<0.01)	0.025
	Group-II	0.05	0.67	0.15	0.326	0.748 (>0.05)	

Table 10: Assessment Results of Effects of Therapy on Laboratory Parameters

Variable	Group	Mean Score		Percent Change
		BT	AT	
Hb	Group-I	12.77	12.81	0.31%
	Group-II	11.98	11.87	0.95%
TLC	Group-I	7097.50	7099.00	0.02%
	Group-II	7171.42	7170.38	0.01%
Neutrophils	Group-I	58.86	59.57	1.20%
	Group-II	23.54	23.72	0.76%
Mixed cells	Group-I	9.18	9.22	0.38%
	Group-II	12.87	12.81	0.46%
Lymphocytes	Group-I	31.40	31.85	1.41%
	Group-II	24.49	24.50	0.02%
ESR	Group-I	20.00	19.26	3.72%
	Group-II	13.33	13.32	0.13%
FBS	Group-I	94.90	93.65	1.31%
	Group-II	92.38	94.00	1.75%
B. Urea	Group-I	23.20	23.12	0.36%
	Group-II	31.43	31.44	0.01%
S. Creatinine	Group-I	0.93	0.91	1.62%
	Group-II	0.98	0.97	0.61%
S. Cholesterol	Group-I	176.60	174.20	1.35%
	Group-II	166.57	166.85	0.16%
S. Triglycerides	Group-I	135.75	134.25	1.10%
	Group-II	133.38	133.79	0.31%
HDL	Group-I	55.11	56.00	1.64%
	Group-II	67.91	67.38	0.77%

LDL	Group-I	93.27	92.11	1.24%
	Group-II	101.38	102.14	0.75%
VLDL	Group-I	29.18	28.77	1.41%
	Group-II	27.54	27.75	0.76%
SGOT	Group-I	35.46	33.84	4.56%
	Group-II	35.24	35.20	0.11%
SGPT	Group-I	38.00	36.94	2.79%
	Group-II	34.57	34.33	0.70%
S. Proteins	Group-I	6.95	7.01	0.81%
	Group-II	6.81	6.80	0.14%

Table 11: Statistical Analysis on Laboratory Parameters

Variable	Group	Mean Diff.	SD+	SE+	't' value	'p' value	Intergroup p-value
Hb	Group-I	0.04	0.04	0.07	0.577	0.571 (>0.05)	0.478
	Group-II	0.11	0.35	0.07	1.492	0.151 (>0.05)	
TLC	Group-I	1.50	1953.57	436.83	0.235	0.817 (>0.05)	0.376
	Group-II	1.04	1399.61	305.42	1.887	0.151 (>0.05)	
Neutrophils	Group-I	0.71	14.08	3.15	0.581	0.568 (>0.05)	0.765
	Group-II	0.18	5.81	1.27	0.682	0.522 (>0.05)	
Mixed cells	Group-I	0.04	5.04	1.13	0.218	0.830 (>0.05)	0.661
	Group-II	0.06	3.91	0.85	0.441	0.664 (>0.05)	
Lymphocytes	Group-I	0.45	12.27	2.74	0.162	0.873 (>0.05)	0.949
	Group-II	0.01	4.92	1.07	0.242	0.811 (>0.05)	
ESR	Group-I	0.74	10.04	2.25	1.292	0.212 (>0.05)	0.873
	Group-II	0.01	8.69	1.89	1.281	0.220 (>0.05)	
FBS	Group-I	1.25	16.40	3.67	1.159	0.261 (>0.05)	0.530
	Group-II	1.62	9.47	2.07	0.784	0.442 (>0.05)	
B. Urea	Group-I	0.08	5.36	1.19	0.901	0.372 (>0.05)	0.604
	Group-II	0.01	6.42	1.40	1.871	0.075 (>0.05)	
S. Creatinine	Group-I	0.02	0.18	0.04	1.580	0.131 (>0.05)	0.298
	Group-II	0.01	0.34	0.07	2.025	0.056 (>0.05)	
S. Cholesterol	Group-I	2.40	32.47	7.26	1.818	0.085 (>0.05)	0.197
	Group-II	0.28	13.82	3.02	1.011	0.393 (>0.05)	
S. Triglycerides	Group-I	1.50	40.12	8.97	1.789	0.090 (>0.05)	0.189
	Group-II	0.41	12.55	2.74	1.373	0.180 (>0.05)	
HDL	Group-I	0.89	8.35	1.87	0.565	0.576 (>0.05)	0.898
	Group-II	0.53	5.22	1.14	1.171	0.255 (>0.05)	
LDL	Group-I	1.16	36.45	8.15	0.871	0.395 (>0.05)	0.473
	Group-II	0.76	16.32	3.56	0.124	0.833 (>0.05)	
VLDL	Group-I	0.41	13.26	3.10	0.360	0.723 (>0.05)	0.682
	Group-II	0.21	11.32	2.47	0.208	0.837 (>0.05)	
SGOT	Group-I	1.619	3.83	0.86	1.652	0.710 (>0.05)	0.364
	Group-II	0.038	18.48	4.03	0.106	0.916 (>0.05)	
SGPT	Group-I	1.063	21.88	5.02	0.650	0.521 (>0.05)	0.603

	Group-II	0.242	6.88	1.50	0.704	0.493 (>0.05)	
S. Proteins	Group-I	0.06	0.50	0.12	1.133	0.270 (>0.05)	0.061
	Group-II	0.01	0.49	0.11	1.604	0.120	

DISCUSSION

The present clinical study was aimed to assess the efficacy and safety of *Amalakavleha* as *Rasayana* in healthy individuals.

Among treadmill test parameters it was observed that after the completion of eight weeks of therapy the mean value of duration of exercise in Group-I increased from 8 min 58 sec to 9 min 28 sec with an increase of 8.15%, mean value of Max. Work Load attained before the treatment was 10.195 Mets which increased to 11.11 Mets after the completion of therapy with 8.97% increase, mean value of VO2 Max before treatment was 36.251ml/ kg/min which increased to 37.749ml/kg/min with an increase of 4.10%, RPP before treatment was 23045.63mmHg. Hz which increased to 24603.2mmHg. Hz after treatment with 6.75% rise. All the results were statistically significant ($p < 0.01$) in Group-I and in Group-II mean value of exercise time before treatment was 6 min 56 sec which reduced to 6 min 54 sec after the completion of therapy with a decline of 0.30%, mean value of Max. Work Load attained before the administration of treatment was 9.881 Mets which decreased to 9.705 Mets after completion of therapy with change of 1.78%, mean value of Vo2 increased from 34.414ml/kg/min to 34.468ml/kg/min. with a negligible increase i.e. 0.15%, mean value of RPP before treatment was 22106.05mmHg. Hz which increased to 22152.57mmHg. Hz after the completion of therapy with a change of 0.21%. All the results were statistically insignificant ($p > 0.05$) in Group-II (Table No.-4)

The intergroup comparison of effect of therapy on all TMT parameters revealed a statistically significant difference ('p' <0.01). (Table No.-4)

Among 20 study subjects registered under Group–I the mean value of foot thrust before treatment was 65.60Kg which increased to 66.90Kg after treatment with an increase of 1.98% which was statistically significant and among 21 study subjects registered under Group–II, the mean value of foot thrust before treatment was 61.81Kg which decreased to 60.91Kg after the completion of therapy with a change of 0.15% which was statistically insignificant ($p > 0.05$). Mean value of hand grip power in Group-I increased to 95.95 mm of Hg from 92.50mm of Hg with an increase of 3.72% which was statistically significant and in Group–II, it was found that the mean value of hand grip power decreased to 93.75mm of Hg from 94.60mm of Hg with a change of 0.90% which was statistically insignificant. In Group–I mean value of body weight before treatment was 65.80Kg which increased to 65.81Kg after treatment with a negligible change of 0.01% and in Group–II, the mean value of body weight decreased from 63.14Kg to 63.08Kg with a change of 0.1%. However the results were statistically insignificant in both the groups. In Group–I the mean value of BMI increased negligibly (0.02%) from 22.36Kg/m^2 to 22.37Kg/m^2 and results found were statistically insignificant. In Group–II also statistically insignificant reduction in the mean value of BMI was observed i.e. from 22.13Kg/m^2 to 22.12Kg/m^2 with decline of 0.06%. In order to assess the respiratory endurance the study subjects were asked to perform the spirometery test and in Group–I vital capacity showed statistically significant increase of 1.32% with rise in mean value from 3.54L to 3.59L and in Group–II change of 0.29% was observed with increase in mean value from 3.35L to 3.36L which was statistically insignificant (Table No.-5)

Intergroup comparison of foot thrust and hand grip power revealed statistically significant difference whereas, intergroup comparison of body weight, BMI and vital capacity showed statistically insignificant difference (Table No.-5).

In the present study, WHO questionnaire was adopted for the assessment of subjective parameters (Table No.-3). It was observed that statistically significant improvement was obtained on overall health (32.2%) and energy (24.5%) in Group-I. Group-II which was the placebo group showed statistically insignificant results both for overall health (3.09%) as well as for energy (1.70%). Statistically significant results were obtained in Group-I on parameters like interpersonal activities (36.6%), mental status (29.6%) and sleep (35.5%). However Group-II showed statistically insignificant results for all these mentioned parameters (Table No-6). The effect of therapy on cognition had statistically significant results in Group-I (27.5%) and statistically insignificant results in Group-II (4.45%). The statistical analysis of the effect of therapy on self care revealed that both the groups had statistically insignificant results but the improvement in Group-I (11.4%) was better than Group-II (4.8%). Effect of therapy on mobility

showed statistically significant results in Group-I with improvement of 36.30% whereas Group-II (5.60%) revealed statistically insignificant results. Hence statistical analysis of the data showed significant improvement in parameters like overall health, sleep, energy, interpersonal activities, mobility, and mental status in Group –I, where as statistically insignificant results were obtained in the parameters like self care, cognition in both groups. The intergroup comparison showed statistically significant difference on overall health, sleep, energy, interpersonal activities and mental status and statistically insignificant results on mobility, cognition and self care (Table No.-6).

Various laboratory investigations including Hb, TLC, DLC, ESR, FBS, Blood urea, Serum creatinine, SGOT, SGPT, S. Lipid profile (S. Cholesterol, S. Triglycerides, HDL, LDL, VLDL), S. Proteins were within normal range both before and after the therapy in both the groups and statistically insignificant changes were observed in these Lab. parameters in both the groups after the therapy. (Table No. 7)

The above results showed positive changes in Group-I in which *Amalakavleha* was administered as *Rasayana* which contains *Amalaki, Pippali, Go-Ghrita* etc. (Table No.-1). Amalaki is commonly used drug in Ayurveda to promote longevity.[4] It has been considered as a very good *Rasayana*. *Amalaki* has *Madhuar Rasa*, *Guru Guna, Sheeta Veerya* and *Madhura Vipaka* which helps in the formation of Rasa of the best Quality.[5] This Rasa further helps in the formation of excellent *Dhatus* which further promotes our physical fitness and overall health. Its *Amla, Madhura, Katu, Tikta, Kashaya Rasa* and *Sheeta, Ruksha guna* makes it superior fruit among all fruits.[6] It helps in amplification of *Agni*[7]; Augmented *Agni* removes the *Ama* from body, improves the metabolism, helps in *Strotoshodhana*[8] that further helps the *Rasa* to nourish *Dhatus* properly, leading to formation of *Ojas*[9]. *Amalaki* has a variety of flavonoids, abundance of Vit C, iron, phosphorous which helps in the better functioning of enzymatic reactions and hence helps in improving overall health and boost up our energy. It has tannoids, gallic acid, ellagic acid, corilagin which not only reduce the oxidative stress in the body but also possess cardioprotective activities.[10] It also helps in improving the memory and intellect by enhancement of gabaminergic metabolic activity.[11]

Pippali is one of the *Rasayana* drugs which specifically act at the level of *Jatharagni* and *Dhatvagni*.[12] It promotes longevity, strengthens the immune system and reduces oxidative stress.[13] It has *Katu Rasa* and *Ushana Guna* acting at the level of *Agni*[12], which further embellishes the metabolism leading to an improved structural and functional pattern of *Dhatus*. *Pippali* has the capacity to mitigate the *Agnidushti* by its *Deepana, Pachana,*[13] *Vrinhana, Shodhana Karma* and hence plays an important role in release of metabolic heat energy. *Pippali* has *Madhuar Vipaka*[12] that promotes the nutritional value of *Rasa* which further helps in the formation of best quality *Dhatus*[14] and finally *Ojas*, which is the main immune-modulator in the body. *Pippali* also alleviates vitiated *Vata Dosha*[13], which is responsible for degenerative changes in body thus protecting body from oxidative stress. It contains Piperine, Piplartine, Piper legumine as primary constituents. Additional active chemicals includes several piperidine alkaloids, terpenines, sesamine etc. which makes it powerful stimulant of various systems of body like digestive, respiratory system.[15] Significant protection against oxidative stress and cardiotoxicity by virtue of its antioxidant activity was also concluded.[16] Its adaptogenic property helps our body to adapt to various physical and mental stress.[17] The ethanol extract of the *P. longum* fruit yields antihyperlipidemic activity.[18] *Pippali* also acts as brain tonic,[19] antidepressant activity of *Piper longum* has been also reported in some studies.

Ghrita has *Madhura Rasa, Guru, Snigdha, Sheeta Guna, Sheeta Veerya* and *Madhura Vipaka*.[20] By virtue of these properties it acts as tissue enhancer, *Medhya, Balya, Ayushya, Ojovardhaka, Rasayana, Vayaasthapka.*[21] *Agni Deepana* action due to *Prabhava* of *Ghee* vitalizes the metabolism. Traditional texts also designate Cow *Ghee* as a *Medhya Rasayana* beneficial for mental alertness and memory.[20] It also possess antioxidant, immune modulator activities, and promotes longevity[21].

Honey *(Madhu)* has *Madhura* and *Kashaya Rasa*, *Ruksha Guna*, *Sheeta Virya* which helps in *Tridosha Shamana*[22] and hence balances the pillars of body i.e., *Vata, Pitta*, *Kapha*. Due to *Ruksha Guna* and *Lekhana Karma* honey penetrates micro channels and cleanses the channels for better circulation of *Rasa*. Honey nourishes the body with its *Vrinhana Guna.* Natural honey contains flavonoides such as apigenin, pinocembrin, quercetin and heopertin etc, phenolic acid (such as ellagie, caffieic, P-coumaric & ferulic acids) ascorbic acid, tocopherols, catalase, superoxide dismutase, reduced glutathione. Anti-oxidant activity of honey is determined by vitamin C, monophenolios, flavonoids and polyphenolies. Phenolic compound present in honey has promising cardioprotective

effect.[23] It assists the building and development of entire central nervous system which leads to the improvement of memory and growth, reduction of anxiety and enhancement of intellectual performance.[24] Anti- ageing potency of honey in white Whister albino rats was also studied which suggested that honey consumption may augment defence mechanism against oxidative stress and various attenuated free radicals.[25]

CONCLUSION

The trial drug showed promising improvement on various subjective and objective parameters related to physical and mental health. Statistically significant improvement in various TMT parameters like exercise time, maximum work load attained, Vo2 max, RPP and vital capacity was noticed in the individuals who were treated with *Amalakavleha* as compared to the placebo group. Statistically significant improvement in most of the subjective parameters like overall health, energy, mobility, sleep, interpersonal activities and mental status were also observed in the individuals who were given *Amalakavleha* as compared to the individuals receiving placebo.

Hence we may conclude that *Amalakavleha Rasayana* is effective in increasing the general physical and mental fitness of an individual.

No untoward effect of therapy was seen during the entire trial period. Though the results of this study are encouraging, a multi-centric study with larger sample size should be conducted to further establish the efficacy of drug. Longer duration trial can be done to evaluate the safety of drug in long term use.

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