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ORIGINAL ARTICLE **OPEN ACCESS**

A Single Arm Clinical Trial to Evaluate the Efficacy of Vrikshamla (*Garcinia cambogia*) in Sthoulya (Obesity) W.S.R. to Hyperlipidemia

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ABSTRACT

Metabolic syndrome is the burning health issues in the current generation, which is leading into grave health problems to all the humankind, as the individual is falling into a trap of sedentary life style which is acting as the prime factor in concerning the circumstances of metabolic syndrome which compromises of the foremost leading condition is Obesity& Hyperlipidemia". The exact pathogenesis and management of this chronic health hazard is still evolving in biomedical sciences. However, it is believed that Obesity &Hyperlipidemia imparts a major role in the diathesis of Metabolic syndrome and warranting special attention regarding its management. Ayurveda emphasizes that "SantarpanotthaVikaras" (diseases due to excessive nutrition) are crucially increasing in these prevailing days due to the intellectual blasphemy of human. Kapha and medodusti (disorders of fat metabolism) serves as one of the imperative etiological factor in manifesting the diseases like stholuya and medoroga, it's also causing the most of the burning disorders, which includes CAD, CVA, and also ischemic heart disease and the list goes on. Impairment in the fat metabolism, when this is not tackled on time it will lead to retention and deposition of serum lipids takes place which is considered as hyperlipidemia, resulting in decreased flow of blood in coronary arteries being the underlying cause to IHD and other such disorders. Hyperlipidemia is identified as one of the leading causes of morbidity & mortality worldwide in both developing and developed countries. Conventional and herbal drugs are being used to lower the levels of serum cholesterol to prevent this menace. In this regard an attempt has been made to critically review the Medohara and Lekhaniyaproperties of drugs which are mentioned in respective Ganas (group of drugs) cited in Brutrayees. Vrikshamla which is explained in Amradi Phala Varga which is highlighted with karma aushadi by bhavamishra who authored bhavaprakashnighantu. Vrikshamla (Garcinia cambogia) which is having the amla rasa pradhana, rukshaguna, usnavirya, amlavipaka and kaphavatahara in nature. Having these properties vrikshamla has been taken up as trial drug in the present study against Hyperlipidemia. That may abet our understanding of prevention and management of Sthoulya (Obesity) and its complications. Administration of drug possessing in present clinical study 60 patients were randomly selected and Vrikshamla (Extract) were given respectively for 60 days. After the completion of clinical trial Vrikshamla(Extract) isquite effective in relieving both Subjective and Objective parameter and found to be statistically highly significant with 'p' value < 0.001.

Keywords: *Sthoulya, Obesity, Hyperlipidaemia, Vrikshamla (Garcinia cambogia)*

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INTRODUCTION

Ayurveda believes that human being is an epitome of universe and is basically composed of same elements that are known as five basic elements namely *Prihvi* (Earth), *Apa* (Water), *Teja* (Fire), *Vayu* (Air) and *Akasha* (Space or Atmosphere). All the five elements are called as *Panchamahabhuta*; around the axis of *Panchamahabhuta* three pillars of life are revolved. The basic principle of Ayurveda stands on *Tridoshas Vata, pitta* and *kapha.* These tridoshas are the basic constituents at the physiological system. These tridoshas are basic metabolic elements constituting the body and mind of the living organisms.

In this most advanced modernized era, the humans are gifted with lot of difficulty, luxuries but at the same time left with sedentary ways of life, stress induced. Unhealthy schedules these along with unsystematic dietary habits, overeating, consuming processed high quality, high caloric foods and beverages propping into one's life are strongly influencing the homeostasis leading to the exhibition of number of pathologies one amongst them being *sthoulya* (obesity). As we moved into rapid upgrading by providing almost luxury to our day-to-day life, an average of person is unable to maintain individual is health by not adopting proper dietary and daily activities as a result of which mainly diseases such as *sthoulya* (Obesity) or *medoroga* occur. Over the scrutinizing of ayurvedic literature it is observed that some of the chapters has been dedicated exclusively elaborated on sthoulya and medoroga several times and in various aspects. Person suffering from sthoulyaroga will be leading a miserably pathetic life, in sthoulyaroga vitiation of doshas takes place, due to hampered daily activities and lack of physical activity, which hampers the sexual life of an individual, individual will be prone to many grave diseases & above all it leads to decreased life span. It has been accepted by all the systems of medicines as well as whole world that obesity is an upcoming burning problem, mostly in wealthy societies and developed nations, but it would be a semi false statement in present day world scenario. Because lot of demographical studies now have revealed that developing and third world countries are no exception in exhibiting obesity. An abstract read "Obesity is not just a disease of developed nations. Obesity levels in some lower income and transitional countries are as high as or higher than those reported in United States and other developed countries and those levels are increasing rapidly. Shifts in diet and activity are consistent with these changes but little systematic work has been done to understand all the factors contributing to these high levels."

It is widely acknowledged that obesity has emerged as an epidemic in developed countries. It continues to be an issue of great concern. In addition, we now face the emergence of obesity as a worldwide phenomenon, affecting wealthy and middle-income people a like in middle income countries as well as residents of countries previously considered to be poor. Obesity is excessive enough to cause many define this as an Epidemic. The major risk related with *sthoulya*(Obesity) is that it favours various complicated pathologies like *prameha, kusta, Swasa, kasa, Vataroga, Kamala* etc. it is a well-established fact that obesity invites life threatening complications like Cardiac diseases, Hypertension, Diabetes mellitus, Atherosclerosis, Strokes, Gall bladder diseases etc. obesity is a chronic disorder, if unrestricted will reduce the life expectancy and contributes to the increasing rate of morbidity and mortality, so it is wisely said, "Longer is the belt shorter is the life".

Therefore, Hyperlipidemia may be correlated with the conditions of *Santarpana-janya-vikara* [1-5] as explained in our classics (Ch.Su.23). So for Concept of Hyperlipidemia is the excess accumulation of lipids (Especially plasma lipids) in the body, leading various acute or chronic condition. "*Ayurveda* classics have also referred that "*prayaha-snehatmedaha pravardhayet"* [6] (M.Ni.34/3-7)

Implying the fact that excess *sneha* is responsible for excess production of *meda* and such excessively produced *meda* causing *avarodha or avarana* of other, *Dhatu* leading to *Medoroga or sthoulya-laxana* as well as *upadrava,* here we can link the *vikruti* which is explained in *Ayurveda* with present modern knowledge about lipids. Therefore, need and relevance of proposed research study for obesity or Hyperlipidemia is a common disorder in recent days, it affects about 28% of total population, mostly the people of developed countries as well as developing countries are said to be suffering from this condition.

Blood levels of cholesterol and triglycerides give valuable information for the assessment of errors in lipids-metabolism**.**

Various surveys in USA and European countries have shown a definite correlation between a high incidence of coronary heart diseases (CHD) and raised cholesterol and triglyceride levels in the body, conversely in some western countries the average of cholesterol level is low, as well as the incidence of CHD. In India the incidence of Hyperlipidemia and related disorders are increasing every year as the evidence of positive correlation between LDL cholesterol and cardiovascular diseases (CVD). There is even stronger negative correlation with HDL higher the plasma HDL level, the lower risk of CVD.

Diagnosis of Hyperlipidemia is done by clinical and laboratory investigations, if Hyperlipidemia is diagnosed. The prime aim is to bring back the high cholesterol level to normal levels, the LDL triglycerides and total cholesterol levels should be lowered and HDL level should be increased by diet control and drug therapy which has equal importance in controlling the disease.

Ayurveda acknowledges that the cause of all these conditions are Agni-vikruti, there is an involvement of jatharagni, bhutagni, and dhatwagni. In order to tackle the samprapti of sthoulya scientific approach is essential one and it's achieved by considering ayurvedic line of management, which is comprehensive and rational.

Scrutinizing the literature shows the involvement of ama and viation of the dhatus are noticed. Analyzing the properties of the drug vrikshamla shows the karmagnata(action) of deepana, amapachaniya,

kaphamedohara and its also have the anulomana properties. It also eliminates the accumulated malas from the dhatus and from the srotas as well which cleanses the dhatus and srotas. In the pathology of Sthoulya (Obesity), Kapha is main Dosha and Meda is main Dushya, while Agnimandya occurs at Medodhatvagni level. So the shamanaaushadi which is having the kaphamedohara property and having the efficacy to rectify the function of medodhatvagnimandya is preferred.

So many preparations have been mentioned in our texts for the treatment of MedodhatuVridhi. But keeping in mind easy availability, compatibility, Vrikshamla [7-9] (*Garcinia cambogia*) is preferred in this present case study, the drug that is selected Vrikshamla (*Garcinia cambogia*), is indicated and having better efficacy in undertaking the sthoulya or medovriddhi

AIMS AND OBJECTIVES:

1. To evaluate the Therapeutic effect of Vrikshamla in Sthoulya(obesity).
2. To evaluate the Therapeutic effect of Vrikshamla in medoroga/Santarpanajanya- vikaras.

MATERIALS AND METHODS:

1) Selection of Cases:

The study was conducted on 60 clinically diagnosed patients of Sthoulya (Obesity). The selection of patients was made from OPD Dept. of Kayachikitsa Jain AGM Ayurvedic Medical college and Hospital Varur (Karnataka)

2) Eligibility Criteria:

A) **Inclusion criteria :**

1) Both Males & females were selected
2) Patient were selectedfrom the age group 20-60 yrs
3) Lipid profile level
a) Serum cholesterol. Above -200 mg/dl
b) Serum triglyceride. above -165mg/dl
c) LDL above – 150mg/dl
d) HDL below – 70mg/dl
4) Patient of sthoulya diagnosed according to classical features.
5) Patients with BMI above 27-30Kg/M^2

B) **Exclusion criteria**

1) Patients below the age of 20 years and above the 60 years.
2) Patients undergoing other treatment for sthoulya (obesity).
3) Known cases of Diabetes mellitus (Madhumeha), Hyperthyroidism, Thyrotoxicosis, Nephrotic syndrome, Hypertension, Cardiac patients, Gouty arthritis, Infectious diseases, Endocrinal and CNS disorders.
4) Hepatic Disorders

DIAGNOSTIC CRETERIA: [10-16]

Diagnosis is done based on the lakshanas mentioned in sthoulyaroga, and based on the values of BMI obtained by each patient and by laboratory investigation- lipid profile of each subject.

ASSESSMENT CRETERIA

A) Assessment of Subjective Parameters forFollowing Symptoms were done

1. *Kshudhaaadhikya (Excessive hunger)*
2. *Sphiksthanaudaralambanam*
3. *Pipasaaadhikya (Excessive thirst)*
4. *Kshudrashwasa (Breathlessness)*
5. *Swedaadhikya (Excessive sweating)*
6. *Atinidra (Excessive sleep)*
7. *Daurbalya (General debility)*
8. *Gaurava (Heaviness of the body)*
9. *Alasya (Letharginess)*

B) ***Assessment of objectives Parameters were done based on the following parameters.***

1) Body weight Kg
2) Body Mass Index =BMI =Kg/m^2
3) Body circumference measurements (at upper mid arm, chest, abdomen, waist, hip, Lower Mid thigh, mid calf)
4) Blood pressure
5) Lipid profile Test.
a) Serum Cholesterol above 200mg/dl
b) Serum Triglycrides above 165mg/dl
c) Serum LDL above 150mg/dl
d) Serum HDL below 70mg/dl

DESIGN OF STUDY:

This was single arm open labeled clinical trial study. The study was cleared by the ethical committee of the Parul Institute of Ayurveda, Parul University, Limda Waghodiya, Vadodhara (Gujarat), PIA IECHR No.:

PU/PIA/IECHR/2019/129 and CTRI No.: CTRI/2019/10/021829 done. Informed consent was taken from all the patients before including them in the clinical trial.

Drug Preparation (Vrikshamla Extract): Drug preparation done at GMP certified Ayurvikas research centre, Gadag (Karnataka)

- Sample size 60

Statistical analysis: Wilcoxon Signed Rank Test was applied for Subjective parameters.

Paired 't' test was applied for objective parameters. The result was obtained on subjective and objective parameters is very highly significant i.e. P<0.001.

INTERVENTION:

Preparation of patient

- Deepana & Amapachana was done by administering tab Agnitundivati 2tid for 2days
- Followed by kosthashuddi done by administering Swadishta virechaka churna 2tsp hs for 1 day

Administration of shamanaaushadi

- Vrikshamla (extract) Capsule 500mg 2 BD before meal with Luke warm water

DURATION OF THE STUDY:

- 60 days of intervention period
- Follow up: Follow up will be done in every 15 days.

Obesity or Metabolic Syndrome and Vrikshamla (*Garcinia cambogia*)[17]:

Several research studiesprove that *Garcinia cambogia* have potential to reverse the etiopathogenes is of obesity, dyslipidemia and Metabolic Syndrome. It also minimizes signs and symptoms of these disorders. In Ayurveda this plant is described under AmlaSkandha, and Hridyamahakashaya by Charaka and in Bhavaprakash Nighantu it is explained under Amradiphalavarga in 6th chapter. It is advocated for the management of variety of disorders such as Vatavikara, Kaphajavikara, Hridroga Etc.,

Chemical Composition

The fruits of Vriksamala contains 10% maleic acid and very little quantity of tartaric and citric acid. Garcinia is a rich source of active compounds including garcinol, isogarcinol, xanthochymol, isoxanthoehymol and Hydroxy citric acid. These are flavonoids, benzophenones, xanthones, lactones and phenolic acids. Xanthones are oxygenated heterocyclic compounds present in higher plants. Xanthone nucleus is symmetric and is known as xanthen-9H-ones or 9- xanthenone or dibenzo-y-pyrone [18]. The biological activities of these compounds depend on the different substituent's position and nature. Flavonoids are polyphenolic compounds, which are remarkable group of plant metabolites. The antioxidant and free radical scavenging activity of flavonoids depend on the position of hydroxyl groups and other chemical features [19]. Benzophenones are organic group of aromatic ketones having the parent compound diarylketone, which have wide applications in pharmaceutical industry [20] as the plant has a wide range of biologically active compounds showing broader activity range.

AYURVEDIC PHARMACODYANAMIC

Rasa	:	Madhura, Amla, Katu (Amlarasa dominant)
Gana	:	Ruksha, Laghu
Virya	:	Ushna
Vipaka	:	Amla
Prabhava	:	Hridya,
Doshaghnata	:	Kapha-Vatahar

ASSESSMENT CRITERIA CLINICAL-GRADINGS:(Subjective Parameters)

In the present clinical study all the cases of sthoulya (obesity) was assessed with the specific subjective and objective parameters at a regular interval of 0th, 15th, 30th, 45th & on 60th day.

Symptoms	*Score:*
Absent	0
Mild (irregular)	1
Mild(regular)	2
Moderate	3
Severe	4

All the above symptomatic assessment was done by using Symptom Rating Scale as following:

Subjective parameters:

1. Kshudhaaadhikya (Excessive hunger)
2. SphikSthanaUdaraLambana
3. Pipasaaadhikya (Excessive thirst)
4. Kshudrashwasa (Breathlessness)

5. Swedaadhikya (Excessive sweating)
6. Atinidra (Excessive sleep)
7. Daurbalya (General debility)
8. Gaurava (Heaviness of the body)
9. Alasya (Letharginess)

Observation and Results:

1. Maximum patients were of 51-60 years' age group of 29 (48.34%)
2. Maximum patients were of Sex wise group of male 33 (55.00%)
3. Maximum patients were of Religion wise group of Hindu community 49 (81.67%)
4. Maximum patients were of Married 45 (75.00%)
5. Maximum patients were of Nature of Occupation wise group of sedentary 30 (50.00%)
6. Maximum patients were of Educational status wise group of primary 24 (40.00%)
7. Maximum patients were of Chronicity wise group of >5years 22 (36.67%)
8. Maximum patients were of Economic Status wise group of Rich 34 (56.67%)
9. Maximum patients were of Positive family history wise group of 39 (65.00%)
10. Maximum patients were of Habitat wise group of Rural 31 (51.67%)
11. Maximum patients were of Kosta wise group of Madhyama Kosta 36 (60.00%)
12. Maximum patients were of Type of Agni wise group of Manda Agni 31 (51.67)
13. Maximum patients were of Vyayama Shakti wise group of Avara 34 (56.66%)
14. Maximum patients were of Prakruti wise group of VataKaphajaPrakruti 29 (48.34%)
15. Maximum patients were of Desha wise group of Sadharana Desha 32 (53.33%)
16. Maximum patients were of Diet wise group of Mixed Ahara 37 (61.66%)
17. Maximum patients were of Nidana (Hetu) wise group of AvyayamaNidhana 38 (63.00%)
18. Maximum patients were of Body Weight (Kg) wise group of 81-90 Kg 22 (36.67%)
19. Maximum patients were of Body Height (Cms) wise group of 161-170 Cms 29 (48.34%)

Effect of Therapy:

A) Subjective Parameters:

Showing the pattern of subjective parameters in 60 patients of Sthoulya (Obesity) treated with Vrikshamla (*Garcinia cambogia*)

A. Subjective Parameters:

Table No.1: Showing the results of treatment on KSHUDHA AADHIKYA (Excessive Hunger):

Wilcoxon signed rank test:

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
KSHUDHA_ADHIKYA_BT	60	3.2	0.6587	2	4
KSHUDHA_ADHIKYA_AT	60	2.4833	0.5365	1	3

Test Statistics

		N	Mean Rank	Sum of Ranks	Z	P value	Remarks
KSHUDHA_ADHIKYA_AT-	Negative Ranks	41	21	861	-6.27	0	HS
KSHUDHA_ADHIKYA_BT	Positive Ranks	0	0	0			
	Ties	19					
	Total	60					

A Wilcoxon signed-Rank test indicated that the "Kshudha" After treatment (mean rank = 2.48) was much lesser then the "Kshudha" Before treatment (mean rank = 3.2) and it is statistically significant with T = 861, Z = -6.266 and p < 0.001.

Table No.2: Showing the results of treatment on SPHIK STHANA UDARA LAMBANA:

Wilcoxon signed rank test:

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum

Test Statistics

	N	Mean Rank	Sum of Ranks	Z	P value	Remarks

SPHIK STHANA _BT	60	2.85	0.6331	2	4		SPHIK STHANA _AT -	Negative Ranks	32	16.5	528	-5.44	0	HS
SPHIK STHANA _AT	60	2.2667	0.5783	1	3		SPHIK STHANA _BT	Positive Ranks	0	0	0			
								Ties	28					
								Total	60					

A Wilcoxon signed-Rank test indicated that the "SPHIK STHANA" After treatment (mean rank = 2.266) was much lesser then the "SPHIK STHANA" Before treatment (mean rank = 2.85) and it is statistically significant with T = 528, Z = -5.44 and p < 0.001.

Table No.3: Showing the results of treatment on PIPASA ADHIKYA (Excessive Thirst):

Wilcoxon signed rank test:

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
PIPASA ADHIKYA _BT	60	2.95	0.5652	2	4
PIPASA ADHIKYA _AT	60	2.3167	0.6241	1	3

Test Statistics

		N	Mean Rank	Sum of Ranks	Z	P value	Remarks
PIPASA ADHIKYA _AT - PIPASA ADHIKYA _BT	Negative Ranks	36	18.5	666	-5.85	0	HS
	Positive Ranks	0	0	0			
	Ties	24					
	Total	60					

A Wilcoxon signed-Rank test indicated that the "PIPASA ADHIKYA" After treatment (mean rank = 2.31) was much lesser then the "PIPASA ADHIKYA" Before treatment (mean rank = 2.95) and it is statistically significant with T = 666, Z = -5.85 and p < 0.001.

Table No.4: Showing the results of treatment on KSHUDRA SHWASA (Breathlessness):

Wilcoxon signed rank test:

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
KSHUDRA SHWASA _BT	60	2.6	0.5272	2	4
KSHUDRA SHWASA _AT	60	2.05	0.5652	1	3

Test Statistics

		N	Mean Rank	Sum of Ranks	Z	P valve	Remarks
KSHUDRA SHWASA _AT - KSHUDRA SHWASA _BT	Negative Ranks	31	16	496	-5.41	0	HS
	Positive Ranks	0	0	0			
	Ties	29					
	Total	60					

A Wilcoxon Signed-Rank test indicated that the "KSHUDRA SHWASA" After treatment (mean rank = 2. 05) was much lesser then the "KSHUDRA SHWASA" Before treatment (mean rank = 2.60) and it is statistically significant with T = 496, Z = -5.41 and p < 0.001.

Table No.5: Showing the results of treatment on SWEDA ADHIKYA (Excessive Sweating):

Wilcoxon signed rank test:

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
SWEDA ADHIKYA _BT	60	2.8667	0.5357	2	4
SWEDA ADHIKYA _AT	60	2.3	0.5615	1	3

Test Statistics

		N	Mean Rank	Sum of Ranks	Z	P value	Remarks
SWEDA ADHIKYA _AT - SWEDA ADHIKYA _BT	Negative Ranks	32	16.5	528	-5.551	0	HS
	Positive Ranks	0	0	0			
	Ties	28					
	Total	60					

A Wilcoxon signed-Rank test indicated that the "SWEDA ADHIKYA" After treatment (mean rank = 2.30) was much lesser then the "SWEDA ADHIKYA" Before treatment (mean rank = 2.86) and it is statistically significant with T = 528, Z = -5.507 and p < 0.001.

Table No.6: Showing the results of treatment on ATI NIDRA (Excessive Sleep):

Wilcoxon signed rank test:

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
ATI NIDRA _BT	60	2.9	0.6561	2	4
ATI NIDRA _AT	60	2.3333	0.6289	1	3

Test Statistics

		N	Mean Rank	Sum of Ranks	Z	P value	Remarks
ATI NIDRA _AT - ATI NIDRA _BT	Negative Ranks	33	17	561	-5.667	0	HS
	Positive Ranks	0	0	0			
	Ties	27					
	Total	60					

A Wilcoxon signed-Rank test indicated that the "ATI NIDRA" After treatment (mean rank = 2.33) was much lesser then the "ATI NIDRA" Before treatment (mean rank = 2.90) and it is statistically significant with T = 561, Z = -5.667 and p < 0.001.

Table No. 7: Showing the results of treatment on DAURBALYA (General Debility):

Wilcoxon signed rank test:

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
DAURBALYA _BT	60	2.7333	0.5783	2	4
DAURBALYA _AT	60	2.25	0.5712	1	3

Test Statistics

		N	Mean Rank	Sum of Ranks	Z	P value	Remarks
DAURBALYA _AT - DAURBALYA _BT	Negative Ranks	32	14.5	406	-5.21	0	HS
	Positive Ranks	0	0	0			
	Ties	28					
	Total	60					

A Wilcoxon signed-Rank test indicated that the "DAURBALYA" After treatment (mean rank = 2.25) was much lesser then the "DAURBALYA" Before treatment (mean rank = 2.73) and it is statistically significant with T = 406, Z = -5.209 and p < 0.001.

Table No. 8: Showing the results of treatment on GAURAVA (Heaviness of the Body):

Wilcoxon signed rank test:

Descriptive Statistics

Test Statistics

	N	Mean	Std. Deviation	Minimum	Maximum		N	Mean Ran	Sum of	Z	P value	Remarks

										k	Ranks			
							GAURAVA _AT - GAURAVA _BT	Negative Ranks	31	16	496	-5.35	0	HS
GAURAVA _BT	60	2.9	0.5431	2	4			Positive Ranks	0	0	0			
GAURAVA _AT	60	2.3333	0.4754	2	3			Ties	29					
								Total	60					

A Wilcoxon signed-Rank test indicated that the "GAURAVA" After treatment (mean rank = 2.33) was much lesser then the "GAURAVA" Before treatment (mean rank = 2.90) and it is statistically significant with T = 496, Z = -5.353 and p < 0.001.

Table No.9: Showing the results of treatment on ALASYA (Letharginess):

Wilcoxon signed rank test:

Descriptive Statistics							**Test Statistics**							
	N	**Mean**	**Std. Deviation**	**Minimum**	**Maximum**				**N**	**Mean Rank**	**Sum of Ranks**	**Z**	**P value**	**Remarks**
							ALASYA _AT - ALASYA _BT	Negative Ranks	30	15.5	465	-5.32	0	HS
ALASYA _BT	60	2.7167	0.6132	2	4			Positive Ranks	0	0	0			
ALASYA _AT	60	2.1833	0.5964	1	3			Ties	30					
								Total	60					

A Wilcoxon signed-Rank test indicated that the "ALASYA" After treatment (mean rank = 2.18) was much lesser then the "ALASYA" Before treatment (mean rank = 2.71) and it is statistically significant with T = 465, Z = -5.324 and p < 0.001.

A. OBJECTIVE PARAMETER:

Table No.10:Showing the results of treatment on Chest circumference parameter:

Paired 't' test:

Group Name-Objective Parameters	Mean	N	Std. Deviation	Std. Error Mean
CHEST_CM BT	95.8167	60	8.43618	1.08911
CHEST_CM AT	91.6833	60	8.05803	1.04029

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
CHEST_CM BT - CHEST_CM AT	4.13333	1.01625	0.13120	3.87081	4.39586	31.505	59	0.000

There was a significant difference in the scores for CHEST_CM BT (M=95.81 SD=8.43**)** and CHEST_CM AT (M=91.68 SD=8.05) condition: t(59)= 31.50, p<0.001.

Table No.11: Showing the results of treatment on Abdomen circumference:

Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
ABDOMEN_CM BT	91.4500	60	8.58739	1.10863
ABDOMEN_CM AT	87.6167	60	8.28536	1.06964

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
ABDOMEN_CM BT - ABDOMEN_CM AT	3.83333	0.95964	0.12389	3.58543	4.08123	30.942	59	0.000

There was a significant difference in the scores for ABDOMEN_CM BT (M=91.45 SD=8.58**)** and ABDOMEN_CM AT (M=87.61 SD=8.28) condition: t(59)= 30.94, p<0.001.

Table No.12: Showing the results of treatment on Waist circumference:

Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
WAIST_CM BT	87.8000	60	8.37834	1.08164
WAIST_CM AT	84.2000	60	8.04184	1.03820

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
WAIST_CM BT - WAIST_CM AT	3.60000	1.01179	0.13062	3.33863	3.86137	27.560	59	0.000

There was a significant difference in the scores for WAIST_CM BT (M=87.80 SD=8.37**)** and WAIST_CM AT (M=84.20 SD=8.04) condition: t(59)= 27.56, p<0.001.

Table No.13: Showing the results of treatment on Hip circumference:

Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
HIP_CM BT	97.3500	60	7.87148	1.01620
HIP_CM AT	92.9667	60	7.55537	0.97539

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
HIP_CM BT - HIP_CM AT	4.38333	0.99305	0.12820	4.12680	4.63987	34.191	59	0.000

There was a significant difference in the scores for HIP_CM BT (M=97.35 SD=7.87**)** and HIP_CM AT (M=92.96 SD=7.55) condition: t(59)= 34.19, p<0.001.

Table No.14: Showing the results of treatment on Waist Hip Ratio:

Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
WAIST HIP RATIO BT	0.8962	60	0.04784	0.00618
WAIST HIP RATIO AT	0.9022	60	0.04647	0.00600

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
WAIST HIP RATIO BT - WAIST HIP RATIO AT	-0.00600	0.01440	0.00186	-0.00972	-0.00228	-3.227	59	0.002

There was a significant difference in the scores for WAIST HIP RATIO BT (M=0.89 SD=0. 04**)** and WAIST HIP RATIO AT (M=0.90 SD=0.04) condition: t(59)= -3.22, p=0.002.

Table No.15: Showing the results of treatment on Mid Arm circumference:

Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
MID ARM CM BT	36.5333	60	4.43968	0.57316
MID ARM CM AT	33.4167	60	4.35809	0.56263

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
MID ARM CM BT - MID ARM CM AT	3.11667	0.80447	0.10386	2.90885	3.32448	30.009	59	0.000

There was a significant difference in the scores for MID ARM CM BT (M=36.53 SD=4.43**)** and MID ARM CM AT (M=33.41 SD=4.35) condition: t(59)= 30.0, p<0.001.

Table No.16: Showing the results of treatment on Mid Thigh circumference:

Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
MID THIGH CM BT	55.8667	60	6.12709	0.79100
MID THIGH CM AT	52.2333	60	6.22288	0.80337

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
MID THIGH CM BT - MID THIGH CM AT	3.63333	0.80183	0.10352	3.42620	3.84047	35.099	59	0.000

There was a significant difference in the scores for MID THIGH CM BT (M=55.86 SD=6.12**)** and MID THIGH CM AT (M=52.23 SD=6.22) condition: t(59)= 35.09, p<0.001.

Table No.17: Showing the results of treatment on Mid Calf circumference:

Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
MID CALF CM BT	34.2833	60	3.49378	0.45105
MID CALF CM AT	31.6833	60	3.51506	0.45379

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
MID CALF CM BT - MID CALF CM AT	2.60000	0.61617	0.07955	2.44083	2.75917	32.685	59	0.000

There was a significant difference in the scores for MID CALF CM BT (M=34.28 SD=3.49**)** and MID CALF CM AT (M=31.68 SD=3.51) condition: t(59)= 32.68, p<0.001.

Table No.18: Showing the results of treatment on Weight in Kg:
Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
WEIGHT_KG BT	78.9667	60	9.98298	1.28880
WEIGHT_KG AT	73.7667	60	9.84174	1.27056

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
WEIGHT_KG BT - WEIGHT_KG AT	5.20000	0.97076	0.12532	4.94923	5.45077	41.492	59	0.000

There was a significant difference in the scores for WEIGHT_KG BT (M=78.9 SD=9.98**)** and WEIGHT_KG AT (M=73.76 SD=9.84) condition: t(59)= 41.49, p<0.001.

Table No.19: Showing the results of treatment on BMI:
Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
BMI BT	30.4033	60	2.99655	0.38685
BMI AT	28.4017	60	3.00635	0.38812

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
BMI BT - BMI AT	2.00167	0.38642	0.04989	1.90184	2.10149	40.124	59	0.000

There was a significant difference in the scores for BMI BT (M=30.40 SD=2.99**)** and BMI AT (M=28.40 SD=3.00) condition: t(59)= 40.12, p<0.001.

Table No.20: Showing the results of treatment on Serum Cholesterol:
Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
SERUM CHOLESTEROL BT	281.3500	60	24.87516	3.21137
SERUM CHOLESTEROL AT	213.8667	60	22.51513	2.90669

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
SERUM CHOLESTEROL BT - SERUM CHOLESTEROL AT	67.48333	11.96108	1.54417	64.39346	70.57321	43.702	59	0.000

There was a significant difference in the scores for SERUM CHOLESTEROL BT (M=281.35 SD=24.87**)** and SERUM CHOLESTEROL AT (M=213.866 SD=22.51) condition: t(59)= 43.70, p<0.001.

Table No.21: Showing the results of treatment on SERUM TRIGLYCERIDS:

Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
SERUM TRIGLYCERIDS BT	195.7667	60	25.29579	3.26567
SERUM TRIGLYCERIDS AT	146.6833	60	23.32634	3.01142

Group Name	Paired Differences					t	Df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
SERUM TRIGLYCERIDS BT - SERUM TRIGLYCERIDS AT	49.08333	10.84450	1.40002	46.28190	51.88476	35.059	59	0.000

There was a significant difference in the scores for SERUM TRIGLYCERIDS BT (M=195.76 SD=25.29**)** and SERUM TRIGLYCERIDS AT (M=146.68 SD=23.32) condition: t(59)= 35.05, p<0.001.

Table No.22: Showing the results of treatment on HDL:

Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
HDL BT	48.2667	60	5.55974	0.71776
HDL AT	53.3167	60	5.68522	0.73396

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
HDL BT - HDL AT	-5.05000	1.12634	0.14541	-5.34096	-4.75904	-34.729	59	0.000

There was a significant difference in the scores for HDL BT (M=48.26 SD=5.55**)** and HDL AT (M=53.31 SD=5.68) condition: t(59)= -34.72, p<0.001.

Table No.23: Showing the results of treatment on LDL parameter:

Paired 't' test:

Group Name	Mean	N	Std. Deviation	Std. Error Mean
LDL BT	199.6500	60	22.88055	2.95387
LDL AT	150.5667	60	20.18841	2.60631

Group Name	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
LDL BT - LDL AT	49.08333	10.41721	1.34486	46.39228	51.77439	36.497	59	0.000

There was a significant difference in the scores for LDL BT (M=199.650 SD=22.88**)** and LDL AT (M=150.566 SD=20.18) condition: t(59)= 36.49, p<0.001.

OVERALL EFFECT OF THE THERAPY:

Table No. 24 Showing the Results derived considering subjective parameters in 60 cases of Sthoulya (Obesity)		
Result	**No. of Patients**	**Percentage (%)**
Good Response (75% relief)	30	50.00%
Moderate Response (50%-75% relief)	23	38.34%
Mild Response (25% - 50% relief)	7	11.66%
Poor Response (25% relief)	0	0.00%
Total	**60**	**100.00%**

Graph No. 01 Showing the Results derived considering subjective parameters in 60 cases of Sthoulya (Obesity)

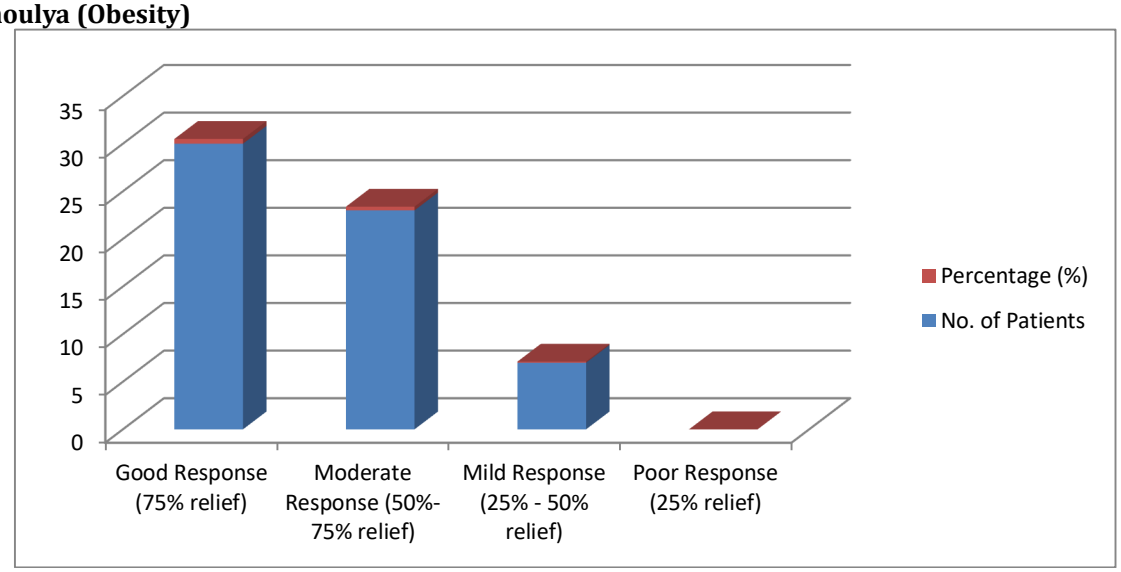
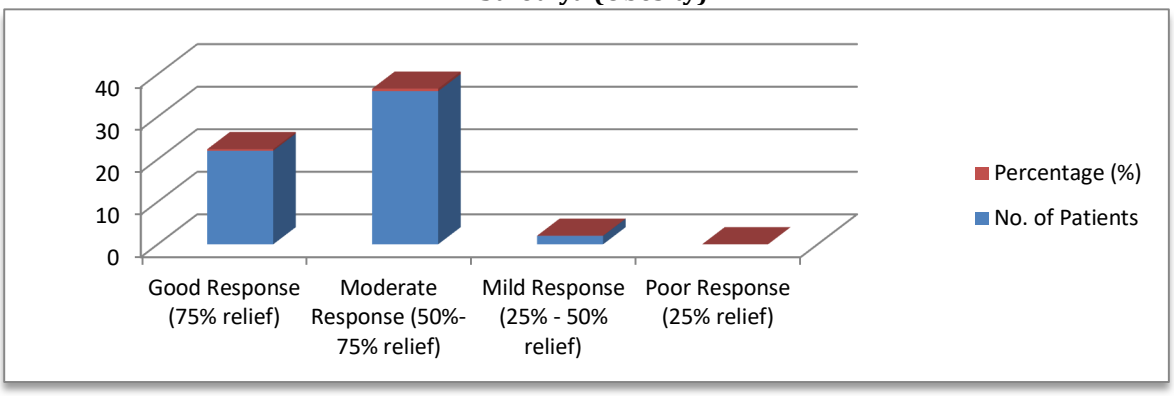


Table No. 25 Showing the Results derived considering objective parameters in 60 cases of Sthoulya (Obesity)		
Result	**No. of Patients**	**Percentage (%)**
Good Response (75% relief)	22	36.67%
Moderate Response (50%-75% relief)	36	60.00%
Mild Response (25% - 50% relief)	2	3.33%
Poor Response (25% relief)	0	0.00%
Total	**60**	**100.00%**

Graph No. 02 Showing the Results derived considering objective parameters in 60 cases of Sthoulya (Obesity)



DISCUSSION

Probable mode of Action of drug of ***Vrikshamla (Extract)****:*

In ayurveda the action of drug is determined on pharmacodynamic factors as Rasa-Guna-Veerya and Vipaka along with certain specific properties called as prabhava (Karma) *Vrikshamla(Extract):* The extract (water based) of Vrikshamla fruits has Amla, Katu and Madhura Rasa. It also has Laghu and UshnaGuna with predominance of Vayu and Agni Mahabhuta. The Deepana, Pachana and Kapha-Medohara properties of Vrikshamla are also mentioned in Ayurvedic literature. Due to its Laghu and UshanaGuna it digest the Amasanchaya and clears the Srotorodha. It contains mainly Amla Rasa which has the property of Agnideepana also predominance of Vayu and Agni Mahabhuta makes it LaghuDravya having inherent tendency of Agnisamdhukshana(Ch.Su.-5/6). So on the basis of these factors it is quite acceptable that Vrikshamla digest the Amasanchaya, clears the Srotorodha and improves the status of Jatharagni and Dhatvagni. Moreover modern science has also shown interest in Vrikshamla. Many studies have shown that intake of HCA present in Kokam reduces appetite, inhibits lipogenesis and reduces body weight

Modern Concept: The active component of *Garcinia cambogia* is Hydroxycitric-acid (HCA). A compound that inhibits the enzyme ATP Citrate lyase. Which is involved in endogenous lipid biosynthesis. Hydroxycitric-acid also increases Hepatic Glycogen synthesis. Suppresses appetite and decreases body weight gain.

CONCLUSION

The present review on Anti-Obesity drug Vrikshamla mentioned inamlaskandain Charaka Samhita and in Bhavaprakasha Nighantuit is described in Amradiphalavarga. The management of Sthoulya/Metabolic syndrome in conventional system of medicine is still not satisfactory and warranting newer strategies from other resources, it seems to explore an Ayurveda inspired line of management for treating Sthoulya (Obesity) or Metabolic syndrome and preventing its life-threatening complications. In the present clinical work Vrikshamla (*Garcinia combogia*) is selected as trail drug for treatment of Sthoulya (Obesity) because of its Medohara (Reduce fat) cardio protective, Anti-Oxidant and lipid per oxidation, in habitation properties. On the basis of clinical observation, it can be concluded that the trial drug Vrikshamla (Extract) showed good results on the subjective and objective parameters like Kshudhaaadhikya, SphikSthanaUdara Lambana, Pipasaaadhikya, Kshudrashwasa, Swedaadhikya, Atinidra, Daurbalya, Gaurava Alasya and Serum Cholesterol, Serum Triglycerides, Serum HDL and Serum LDL Etc., was found to be statistically highly significant with P Value <0.001.

Reduction in body weight was seen in maximum number of patients. A mean reduction of above 10% is noticed which is statistically very highly significant (t=41.49. P <0.001) within short period of time. The above study shows that vrikshamala is one of the best drug which shows a better efficacy in tackling the obesity within a short time of period. Further study on large number of patients with longer duration of study is needed to achieve a definite conclusion.

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