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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF PIPPALI ARKA IN THE MANAGEMENT OF STHOULYA

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ABSRACT

Ayurveda s ancient sysem of medicine which tells in detail about the various vyadhi, aushdhas, anupana, ahara, vihara, for swastha rakshnam and vyadhi upashamana. obesity is a sedentary life style and metabolic disorder. The WHO now considers obesity to be a Global epidemic and a public health problem. Globally an estimated 300 million adults are now obese and many are overweight. Prominent health risks associated with obesity are hypertension, type-2 diabetesmellitus, dyslipidemia, stroke, gall bladder stone, osteoarthritis, respiratory problem etc. The recent statistical data of WHO, shows that the world wide prevalence of Obesity is around 400 million with high rates among women than in men. In India 55% of male, 12.6% of female are obese and the condition is more in urban population than among rural population2. It also poses a major risk for chronic diseases. Obesity not only affects the health and life of the person but also the country's economy. So, it is the need of the hour to develop better treatment protocol to treat and prevent the condition. As per Ayurveda, Acharya Charak has counted Sthoulya under astha Nindita Purusha.Moreever the chikitsa of sthoulya to be done with the apatarpana as medhohara chikitsa in this study the Pippali arka is used as told in arka prakasha. The property of drugs have shown that the Pippali and madhu is found to be effective in Sthoulya. The pippaliand madhu has kaphahara and medohara effects. Concurrently it is also mentioned in Arka Prakasha Pippali Arka along with Madhu that is beneficial in Sthoulya. To assess the effect of pippali arka 30 patients taken for 60 days study with single group, ofter the effect assessed with stastistically method.

KEYWORDS: Madhu, Pippali Arka, Medhohara, Sthoulya, Obesity.

INTRODUCTION

Overweight and obesity are defined as abnormal or excessive fat accumulation that presents a risk to health. A crude population measure of obesity is the Body Mass Index (BMI), aperson's weight (in kilograms) devided by the square of his/her height (in metres). A personwith a BMI of 30 or more is generally considred obese. A person with a BMI equal or more that 25 is considered as overweight.

In the present days the man has to run with the time and he is trying to lead mechanical life. Though he knows the ill effects of such mechanical life, he made himself victim to it by suffering with many disorders, among these sthoulya is a global problem and more common in modernized man and in present era. This sthoulya is considered as Santarpanajanya vyadhi and one among the Ashta nidhita purushas and also as Kaphaja nanatmaja vyadhi. The obesity is the certainly the mother of dangerous diseases1 and most burning problem in the present society. Obesityhas become an epidemic in 21st century2. It is a bitter truth to swallow about every 4thperson on earth is too fat. Weighty women get six times more diseases. Obesity is fast becoming one of the worlds leading reason why the people die. The ancient Indian science of health, Ayurveda is now being increasingly accepted by the world at large for its facilities and adoptability even to the modern times. It is not surprising that, the ancient science is accorded such importance in countries where modern medicine itself has made immense advances. The only reasonable explanation for this phenomenon is the fact that Ayurveda remains the only system of medicine that possesses a natural form of treatment, one that prescribes remedies in accordance with nature itsel Various treatment modalities have been defined for Sthoulya in

our Sahmitas. Among them langhan, swedan, lekhan, guru-apatarpan, Kaphavataghna karma. By this references Sthoulya being a morbid disease Shamana can give a treatment can be better done with proper dosage11, as shamana prevents the relapse of the condition. Hence here an attempt is made to treat Sthoulya with shamanoushadhi. In this study the selected drug Pippali is having laghu, snighda teekshna guna, katu rasa, madhura vipaka and anushnasheeta veerya alon with madhu. Due to these properties it acts as kaphavatahara. so the study is conducted to solve the problems related to sthouly (medhodhathu) with reference of Arka prakasha.

AIM AND OBJECTIVES
1 To evaluate the therapeutic effect of Pippali arka in the management of sthoulya.
2 Evaluation of the effect of Pippali arka in the management of Sthoulya w.s.r.t. weight.
3 Evaluation of the effect of Pippali arka in the management of Sthoulya w.s.r.t. B.M.I.
4 Evaluation of the effect of Pippali arka in the management of Sthoulya w.s.r.t waist Hip ratio.

MATERIALS AND METHODS
SOURCE OF DATA
30 patients of Sthoulya, who are fit for taking pippali arka, will be selected randomly for the study from the OPD and IPD of Ayurvedic medical college & hospital Davanagere or its associated hospitals will be selected after being screened as sthoulya.

SOURCE OF DRUG
All the raw drug is collected from the ashwini pharmacy, and drug prepared in RSBK lab of Ayurvedic medical college & hospital Davanagere.

The ethical clearance available on 21-10-2022.

Study duration of Trial drug
Pippali arka Simple Random sampling technique clinical study was conducted for 60 days. After giving Pippali arka, the internal medicine was dispensed for 15 days to all patients and advised to report for every 15 days interval, noted the nature, frequency and other symptoms during their visits.
1) Follow up of Trial drug Pippali arka trail offered a follow up15 days. The effect of yoga was analyzed according to clinical and functional response before and after the treatment is compared to that of follow up data.

Criteria for diagnosis
· Patients were diagnosed on the basis of Performa prepared with signs and symptoms of Sthoulya in Ayurvedic classics, supported by symptomatology ofObesity.
· Diagnosis of Obesity was undertaken as per LIC /WHO height- weight chart7. A person carrying 10% more weight was selected as Obese.

· Measurement of skin fold thickness8 of TricepsBiceps muscular region and sub scapular region wascarried out by skin fold calipers.
· Body Mass Index (BMI) was calculated. The value ofBMI greater than 25 was considered as obese.

ASSESSMENT CRITERIA
The assessment will be done on the basis of following Subjective parameters and Objective parameters.
• Exercise intolerance •   Dourbalya • Swedabhada
• Dourgandhya • Atikshut
• Body mass index. • Waist hip ratio.
• Anthropometrics (Measuring skin fold thickness by using Harpenden calipers).

Triceps, Biceps, Intra scapular, Sub scapular, Abdomen, Thighs.
• Measurements are taken at various position namely; Chest, Abdomen, Buttocks, Thighs.

INVESTIGATIONS
1Lipid profile
2 BMI PARAMETER.
3 CBC (if necessary)

INCLUSION CRITERIA
• Patients with Pratyatma lakshana of Sthoulya.
• Patients fit for taking Pippali arka.
• BMI > 25kg/m2.
• Patients of either sex aged above 18 years and below 60.
• Irrespective of gender
• Patient having clinical features of Sthoulya viz.
1) Chala sthana 2) Chala udara 3) Chala sphik.

EXCLUSION CRITERIA
•Patients Age of between below 18 and above 60.
•Obesity due to secondary causes.
•Other systemic diseases which intervenes with the course of treatment.
• Mechanical complications of Sthula– hip and lumbar spine developing Osteoarthritic changes.
•Cardiovascular complications of Sthula – Angina pectoris, Hypertension, Cardiac failure.
• Metabolic complications of Sthula – Diabetes, Gout, etc.
• Sthula with secondary causes like endocrinal and C.N.S. diseases.

Source of data of Trial drug
In spite of this much of prevalence and increasing nature of the disease all over the world, still researchers are struggling for a good, effective and harmless remedial

measure of sthoulya. Diet control, exercise, oral lipolytic agents have tried and treated this public health threat, Sthoulya. The data of30 patients was collected from the patients suffering from Sthoulya in the OPD of Ayurvedic medical college and PG centre Davangere.

DRUG REVIEW
The medicament Pippali arka is undertaken for the study, which include Pippali 1part Jala 10parts followed by Pippali arka with mahdu as anupana taken as Pippali arka for this Block box clinical trial.

Ingredients   Quantity
1 Pippali - 1part 2 jala - 10part

In other words madhu due to its prabhava assumes & magnifies gunas of whatever dravya is used along with it. Hence madhu is used along with most of the aharas & aushadhas which are Kaphamedo and mehahara but madhu should be used in small quantities.

DOSE : 10ML Two times a day.
ANUPANA : along with Madhu.
Duration of the Treatment- 60 days.
Criteria for assessment: The results were assessed with regards to improvementrecorded, in clinical findings and laboratoryinvestigations. Changes observed in signs and symptomswere assessed by adopting suitable scoring method andobjective signs by using appropriate clinical tools.

SUBJECTIVE CRITERIA
Chala sthana, udara, and sphik
Grade 0 = Absence of chalatva.

Madhu was used as anupana
Materials and Method of Preparation.
PIPPALI – 1 PART   JALA – 10 PART
To prepare an Arka, Arkayantra(Distillation apparatus) is necessary. The Pippali should be powdered (if dry) or crushed well (if fresh) and soaked for 2-4hrs. with sufficient quantity of water. The well soaked pippali should be transferred to the distillation apparatus and 10 part of water is added to it. The mixture (pippali and water) should be continuously heated till 60% of distillate is collected Then heating should be stopped. After cooling, The collected Arka (distillate) should be filtered and preserved in a air tight bottle.

Grade 1 = Little visible movements (in the areas) after fast movement
Grade 2 = Little visible movements (in the areas) even after moderate movement
Grade 3 = Movements (in the areas) after mild movement
Grade 4 = Movements (in the areas) even after changing posture. Grade 4 = continuously noticed
1) Alasya
2) Kshudra shwasa
3) Dourbalya
4) Nidradhikyata
5) Swedadhikyata
6) Dourgandhya
7) Atipipasa
8) Atikshuda

OBJECTIVE CRITERIA
It was assessed on body weight, measurement of circumference, BMI, and biochemical investigation reports, before starting the treatment and after completion of treatment through percentage relief and statistical evaluations.

Body weight:-Body weight, 10% more than standard weight accordingto LIC chart was recruited as obese.

Measurement of circumference: For present study the circumference measurement of girth of certain region by using measuring tape, before and after treatment was carried out.

Measurement was taken in the following areas as.
Chest: - in normal condition at the nipple region.
Abdomen:-at the level of umbilicus.
Hip:-at the level of highest point of buttock.
Laboratory investigations like lipid profile before and after treatment.

CRITERIA FOR ASSESSMENT
1. Good response   – Reduction in 10 – 15 % of the body weight
2. Moderate response – Reduction in 5 – 10 % of the body weight
3. Poor response   – Reduction in 5 % > of the body weight
4. Not responded   – No change in the body weight.

Statistical analysis
The information gathered on the basis of observation made about various parameters was subjected to statistical analysis in terms of mean standard deviation (SD) and standard errors (SE). Paired t test was carried out at $p<0.05$, $p<0.01$, $p<0.001$. The obtained results were interpreted as-
Insignificant = $p > 0.05$
Significant = $p <0.01$
Lightly Significant = $p < 0.001$

OBSERVATIONS
The study on Pippali Arkka has an equal gender distribution among its 30 participants, with 15 being male (50%), and 15 being female (50%). This balanced representation ensures equal consideration of both gender perspectives, allowing for a comprehensive analysis of results across genders. The total sample size is 30, representing 100% of the study population.

The study on Pippali Arkka found that a majority of participants follow a mixed diet, with a smaller portion adhering to a vegetarian diet. Out of 30 participants, 56.7% consumed a mixed diet, while 43.3% followed a purely vegetarian diet. This highlights the diversity in food habits among the study population.

The study on Pippali Arkka reveals that 70% of the participants are in the "Sedentry" occupational group, with 30% working in "Active" occupations. Out of 30 participants, 70% belong to the "Sedentry" group, while 30% work in "Active" occupations. This occupational breakdown provides insight into the professional backgrounds of the participants, indicating a significant proportion of the study population is engaged in "Sedentry" occupations.

The study on Pippali Arkka reveals a diverse economic distribution among participants. Out of 30 participants, 50% are classified as high-middle, 40% as middle, and 10% as poor. The majority fall into high-middle and middle-income categories. The total sample size is 30, representing 100% of the participants, providing context for understanding the socioeconomic diversity of the study population.
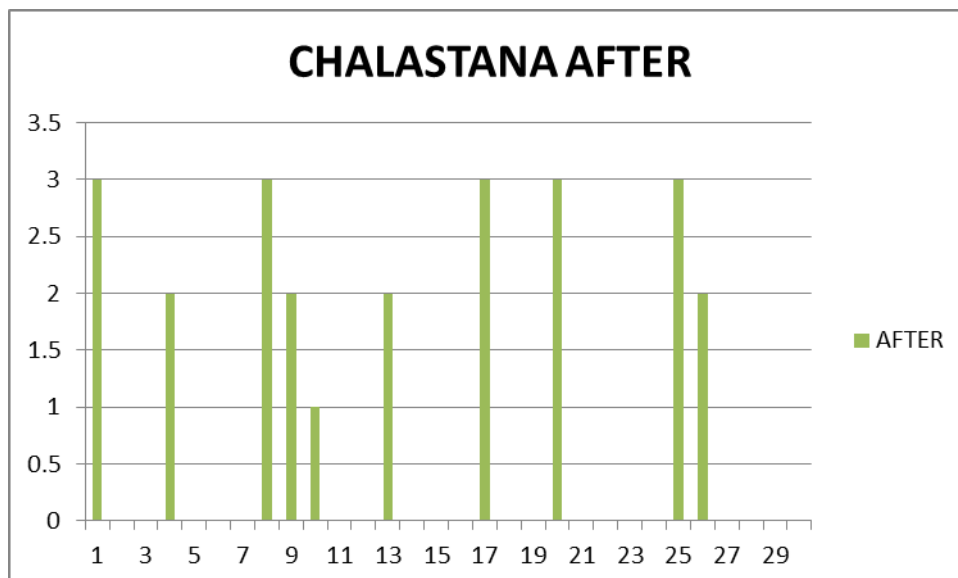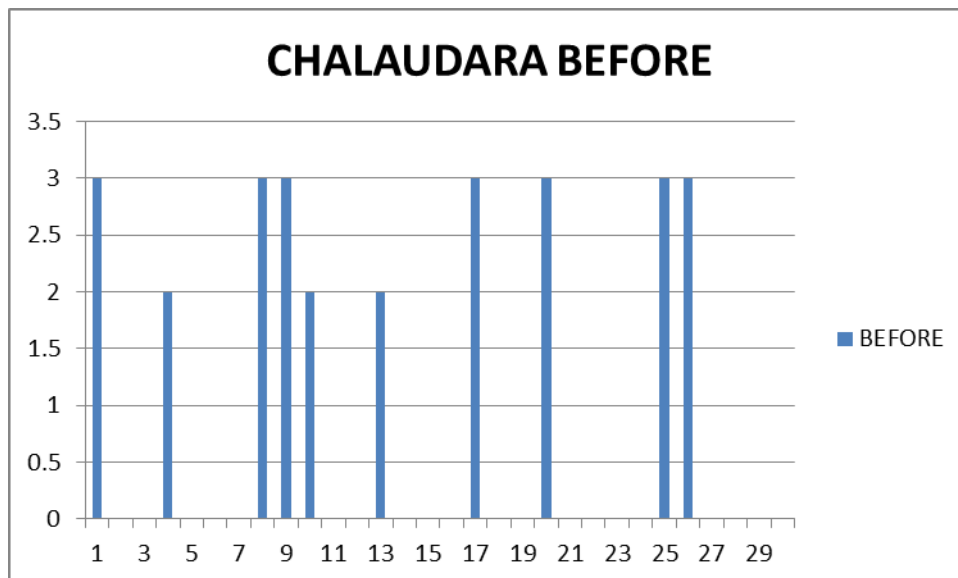
The Pippali Arkka study reveals a preference for sweet, sour, and salty tastes among 30 participants. Sweet tastes are preferred by 80% of participants, followed by sour tastes by 60% and salty tastes by 93.3%. Pungent tastes are preferred by 33.3% of participants, while 66.7% do not. Bitter tastes are preferred by 10% of participants, while 90% avoid them. Astringent tastes are enjoyed by 23.3% of participants, while 76.7% do not. This indicates a strong preference for sweet, sour, and salty tastes, with pungent, bitter, and astringent flavors being less favored. The Pippali Arkka study reveals that 30% of participants have Sama Agni, a balanced digestive state, while 70% do not. Vishama Agni is less common, with 20% of participants having it, while 80% do not. Manda Agni is absent, with none of the participants exhibiting it. Teekshna Agni is present in an equal distribution, with 50% having it and 50% not. This indicates that balanced and irregular digestion are present in the study population, but slow digestion is absent, and a significant number of participants show signs of strong or intense digestion.
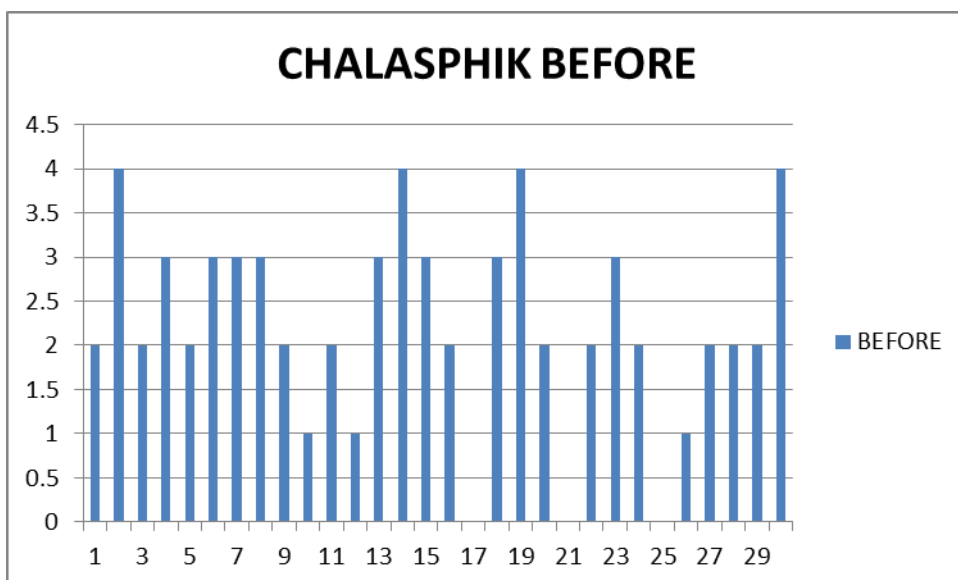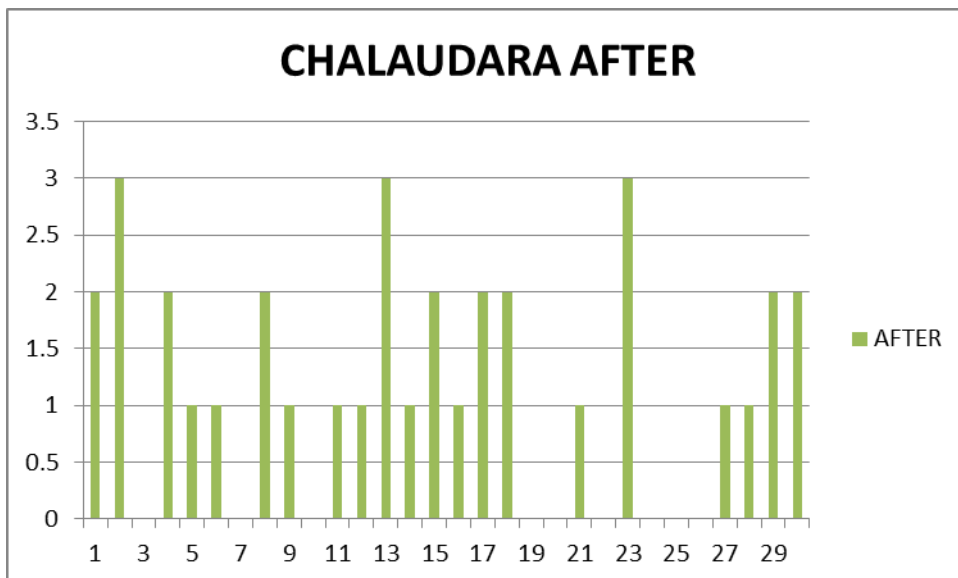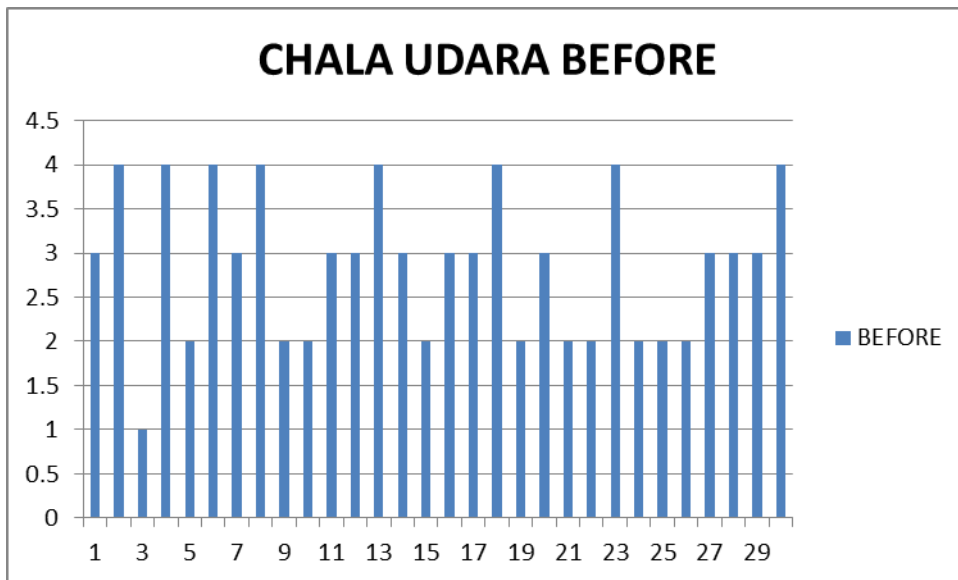
The Pippali Arkka study found that a significant number of participants have either moderate or hard bowel patterns, with a majority of them having either. The data showed that 40% of participants have Mrudu Kostha, indicating a soft bowel nature, while 60% do not. The majority of participants have Madhyama Kostha, indicating a moderate bowel nature, while the majority do not. This indicates that the majority of participants have either a moderate or hard bowel nature.
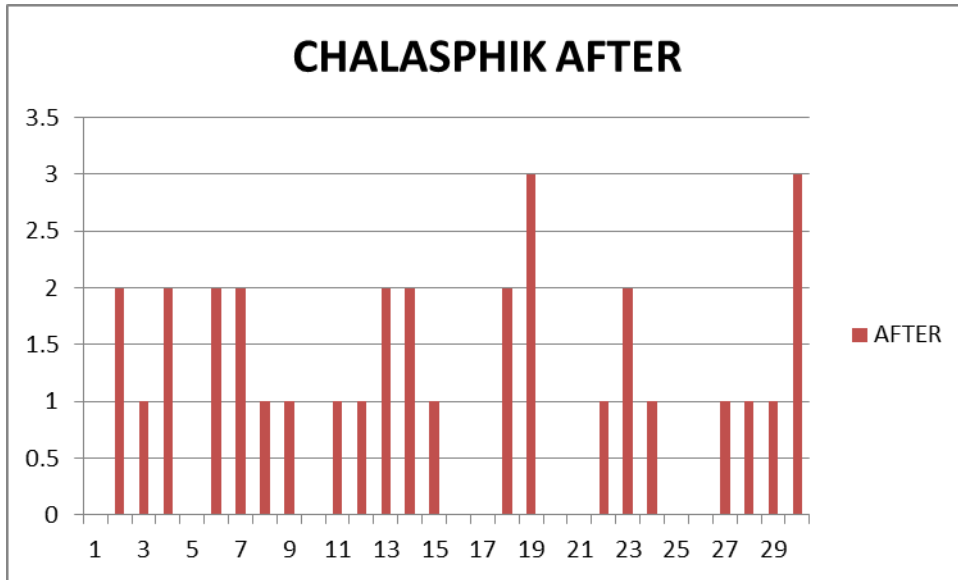
The Pippali Arkka study found that 70% of participants have normal bowel habits, with fewer experiencing loose stools or constipation. The majority of participants (21 out of 30) maintain regularity. However, 16.7% of participants experienced loose stools, while 83.3% did not. Constipation was reported by 13.3% of participants, while 26.7% did not. Overall, the majority of the study population has normal bowel habits, with fewer experiencing these issues.

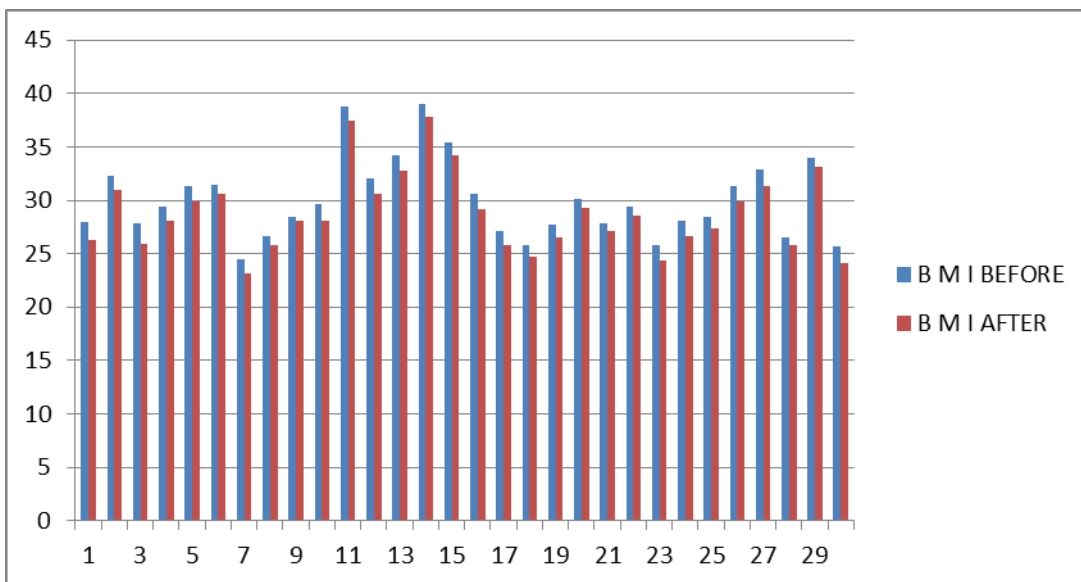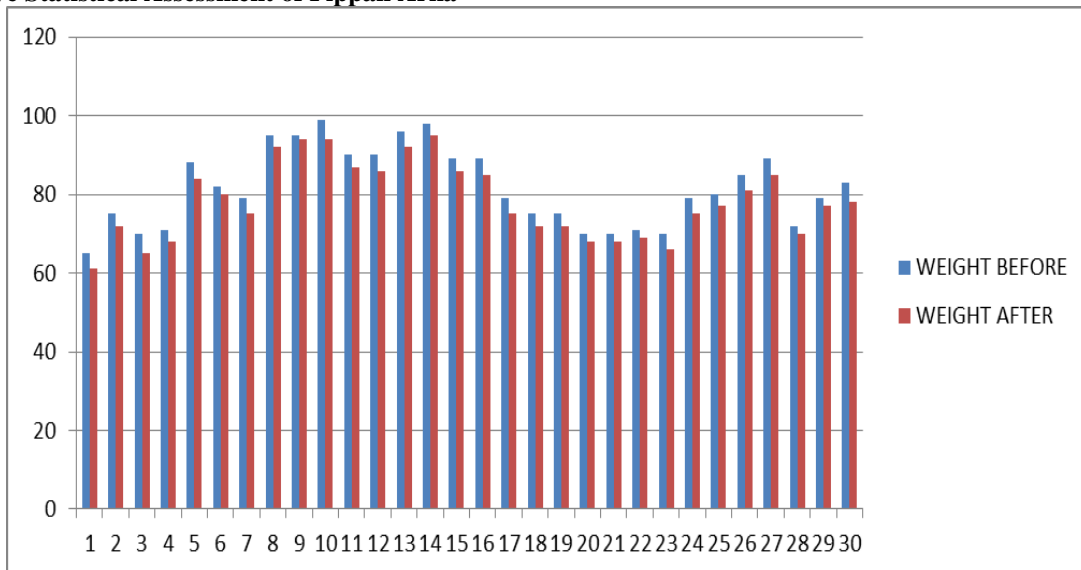**Statistical Assessment of subjective and objective parameters.**

Objective Statistical Assessment of Pippali Arka	Mean	Std. Deviation	Std. Error Mean	t-value	p-value	Significance
Chalasthana - Before	1.00	1.36	.25	1.795	0.083	NS
Chalasthana - After	.90	1.26	.23			
Chalaudara - Before	2.87	.86	.16	13.260	0.000	**HS**
Chalaudara - After	1.17	.98	.18			
Chalasphik-Before	2.23	1.13	.21	9.872	0.000	**HS**
Chalasphik-After	1.10	.92	.17			
Weight-Before	81.60	9.80	1.79	17.683	0.000	**HS**
Weight-After	78.30	9.70	1.77			
BMI-Before	30.00	3.66	.67	18.945	0.000	**HS**
BMI-After	28.79	3.66	.67			
WH Ratio-Before	.8957	.072	.01	6.715	0.000	**HS**
WH Ratio-After	.8087	.067	.01			
SR Cholesterol-Before	193.537	23.66	4.32	2.598	0.015	**S**
SR Cholesterol-After	179.143	37.09	6.77			
SR Triglyceride-Before	152.280	34.02	6.21	1.152	0.259	NS
SR Triglyceride-After	147.743	28.63	5.23			

CHALAUDARA BEFORE

CHALASTANA AFTER

CHALA UDARA BEFORE
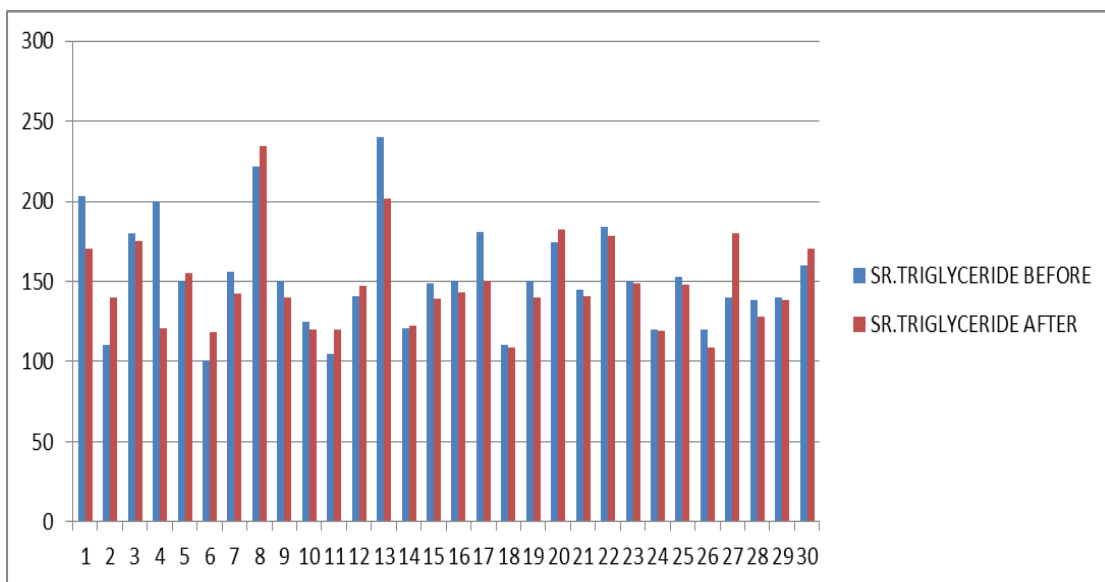

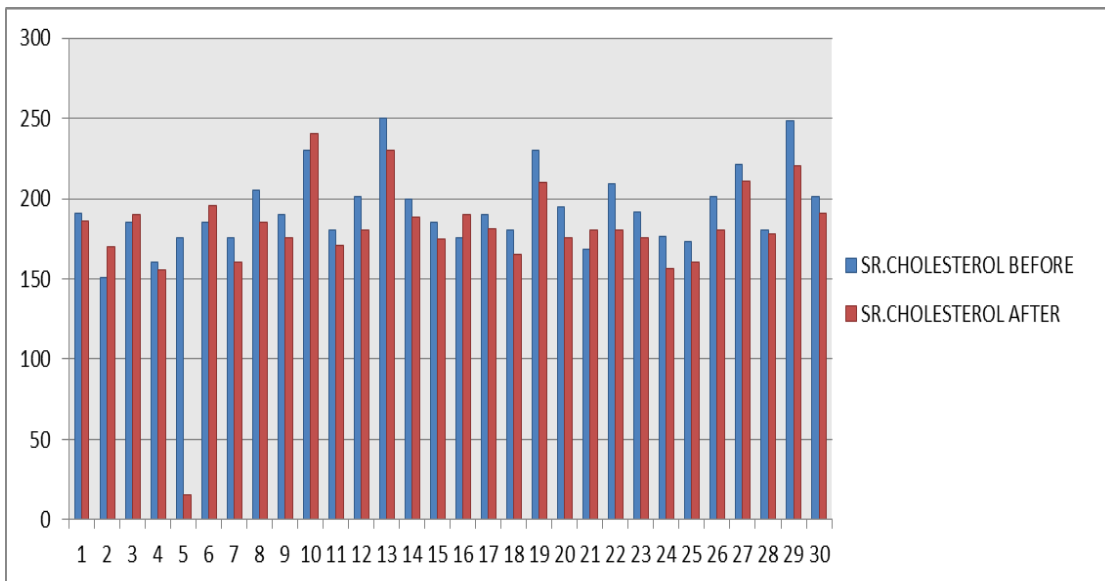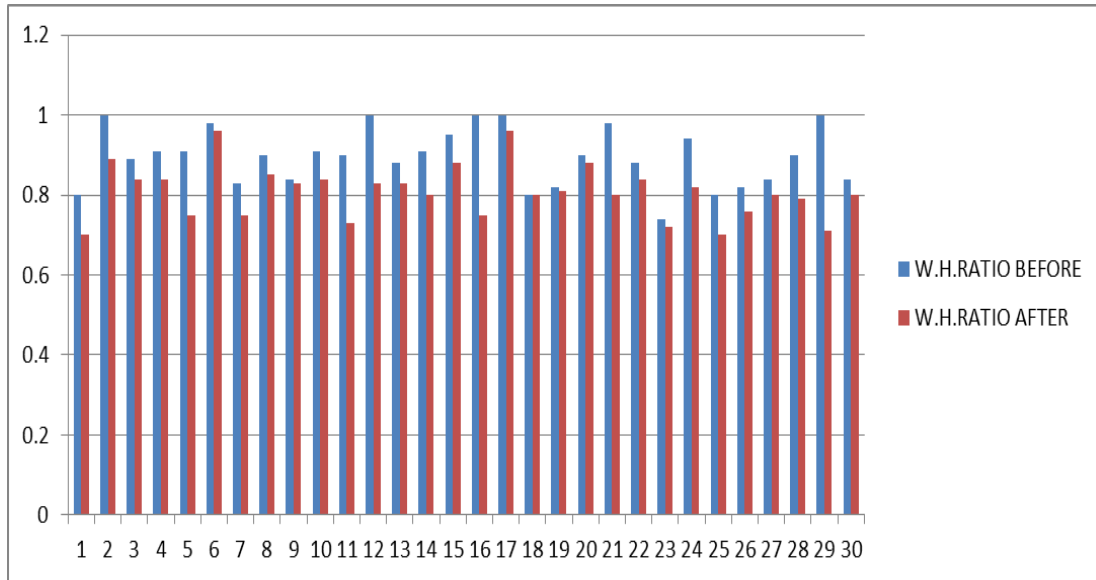## CHALAUDARA AFTER

CHALASPHIK BEFORE

Objective Statistical Assessment of Pippali Arka

The subjective & Objective Statistical Assessment of Pippali Arka reveals significant improvements in various health parameters before and after the intervention. The results show that Pippali Arka has a positive impact on

these health metrics, including Chalaudara, Chalasphik, Weight, BMI, WH Ratio, Serum Cholesterol, and Serum Triglycerides. The assessment shows that the intervention with Pippali Arka has a significant impact on these health metrics. However, no significant changes were noted in Chalasthana and Serum Triglycerides. Overall, the data supports the efficacy of Pippali Arka in promoting better health outcomes among the participants.

DISCUSSION
To discuss about chikitsa, according to Gada nigraha, the sthoulya chikista need mainly alleviation of Vata and Kapha along with depleted Medodhatu by increasing medodhatwagni keeping in view regarding the agni as Charak said ' Laghu cha apatarpana'. But in this study the drugs were selected on the basis of Shushruta's statement on sthoulya chikitsa as chedaneeya and virukshna dravya chikitsa.

The mode of action of trial drug can be analyzed on the basis of three factors.
1) Pharmacodynamics of drugs
2) Chemical composition of drugs
3) Site of action of drugs.

1) Pharmacodynamics of drugs \ Rasapanchaka: Here the drugs of Pippali arka i. Pippali have lagu, snighdha teekshna guna, katu rasa, madhura vipaka and anushnasheeta veerya (these are present commonly in internal medicine). Because of these properties they act on kapha and vata along with madhu is Grahi, vilekhana, srotoshodhaka, deepana relieve the kaphamedohara, which is the main pathology found in manifestation of sthoulya.

The madhu which is used internally as anupana it has kashaya rasa and ruksha guna along with yogavahi property. Hence it helps in reducing meda.

2) Chemical composition of drugs: In latest researches it has been proposed that honey contains a sucralfate like substance that may be responsible for its antioxidant property and gastric protection, deterioration in the processes of lipids peroxidation and rise in the activity of antioxidant system of an organism.

3) Sites of drug metabolism: The metabolizing enzymes are found in most tissues in the body with the highest levels located in the tissues of the gastrointestinal tract (liver, small intestine and large intestine). Drugs that are administered, absorbed by the gut and taken to the liver can be extensively metabolized. The small intestine plays a crucial role in drug metabolism. Since most drugs that are administered orally. In the present trial, treatement is initiated with oral route.

The fluid containing the drug is retained in the GI tract it may act systemically after absorption through the small intenstine. The portion absorbed from the upper and lower GI is carried by the intestinal veins i.e superior and inferior mesenteric veins into the portalcirculations.

CONCLUSION
The subjective & Objective Statistical Assessment of Pippali Arka reveals significant improvements in various health parameters before and after the intervention. The results show that Pippali Arka has a positive impact on these health metrics, including Chalaudara, Chalasphik, Weight, BMI, WH Ratio, Serum Cholesterol, and Serum Triglycerides. The assessment shows that the intervention with Pippali Arka has a significant impact on these health metrics. However, no significant changes were noted in Chalasthana and Serum Triglycerides. Overall, the data supports the efficacy of Pippali Arka in promoting better health outcomes among the participants. It is suggested that further studies should becarried out not only to assess the efficacy of the drug butalso to find out the most effective therapeutic module.Due to certain limitations it was not possible to carry outchemical analysis of formulation. In future apharmacological as well as phytochemical study may be planned.

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