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CLINICAL OPEN RANDOMISED COMPARATIVE STUDY OF VIDANGADI LAUHA AND NAVAK GUGGUL IN MANAGEMENT OF STHAULYA WITH SPECIAL REFERENCE TO OBESITY

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ABSTRACT

Sthoulya is defined in Ayurveda-A Person having heaviness and bulkiness of the body due to extreme growth especially in the Udaradi (Abdomen) region is termed as "Sthula" and the state of Sthula is called as "Sthoulya". Sthoulya has been classified under "Ashta Nindita Purusha"4 (Eight despicable personalities). Ayurveda highlightsSthoulya as Kapha Pradhanaja (predominantly caused due to vitiated Kapha dosha), Medopradoshaja (Meda is the tissue which is predominantly affected), Bahudoshssa Avastha (multi-factorial condition) which can be counted as Santarpanajanyavyadhi (Disease caused due to affected anabolism). The world health organization (WHO) considers obesity as an insidious creeping epidemic that is now engulfing the entire world. Diet and lifestyle play a significant role both in the control and development of obesity. According to WHO, obesity is listed in top ten disorder that causes ill health. According to National Family Health Survey, India has 3 ranked in order of percentage of people and found obesity 14% in male and 16% in female. The Whole World is facing the Problem of Obesity thus this study is an attempt to find a holistic solution to the Disease of Medoroga.In such conditions, when there is excess Meda stored in the body, I have selected Aushadha chikitsa as it will help to reduce excess deposited Meda and symptoms of Sthoulya. In samprapti of sthaulya kapha and vaat dosh is involve and medodushti is seen dominately. So the treatment must be kaphahar vaathara. On that account vodangadi lauha is dominat in kaphahar and vaathar gunna dharma. Navakguggul contain ushanviryadravya and navak guggul which is also medo-vatahara. So this subject "Clinical Open Randomized Comperative Study of Vidangadi Lauha and Navak Guggul in Management of Sthaulya with Special Refrence to Obesity" is selected for study.

KEYWORD: Sthaulya, Vati, Vidangadi Lauha, Navak Guggul.

INTRODUCTION

The prevalence of Sthoulya (Medoroga) is increasing worldwide in all age groups within people of higher socioeconomic status, specifically in urban communities. Maharshi Charak opined healthy state as Proportionate musculature, compactness of the body, proper sensory and motor function.

Ayurveda is the science of Indian tradition of medicine. Today Ayurveda has emerged as an integral part of or daily lifestyle. In today's ayurvedic practice the occurrence of noncommunicable diseases has increased considerably. sthaulya (obesity) is a NCD which is chronic and slow progressing .it is the growing problem of the current era due to modernization and sedentary life style, lack of exercise junk food and improper eating habits. Sthaulya is described under ashtaoniiditiyaadhyay in charak Samhita and is named as niditvyadhi, as a disorder which affects the life span n also quality of life. The modality of treatment available in modern science includes antihyperglycemic drugs etc and finally surgery.

In Integrated medical science, *Sthoulya* is compared with Obesity and is defined as the excess of body fat that possesses a health risk. It is caused by excess calorie intake, endocrine disorders like hypothalamic disorders, Hypothyroidism, Cushing's syndrome etc10. Obesity can also be drug-induced or due to genetic inheritance. Obesity is considered the world's oldest metabolic disorder. It is not a single disease entity but a syndrome having many causes. The causes include combination of three factors genetic, nutritional, and sociological factors. Obesity or being overweight is a condition characterized by excessive storage of fat in the body.

Santarpanottha Vikaras (Disease due to excessive nutrition) is increasing day by day. Medodushti (Disorders of fat metabolism) serves as one of the important etiological factors in most disorders. There are many effective medicines and therapies described in different classics of Ayurveda for treating Sthoulya.

Many lines of treatments are available to treat sthaulya but none seems to give desired result. Thus there is need to find more accurate and economically viable formulation with almost no side effects. This is our attempt to achieve one such medicine. Due to present era of globalization which has taken a toll on lifestyle of people which has made it a more sedentary one coupled with irregularities of the eating habits. Sleeping cycles and routine which contributes towards risk factors of obesity hence this disease needs to be viewed with another prospective of the line of treatment of the therapy. Hence Vidangadi Lauha could be an add-on option in the line of treatment of Sthoulya. So for the comparative study between two drugs, we consider Navak Guggul and Vidangadi Lauha because of their merit and effectivity.

AIM: Whether Vidangadi Lauha is more effective than Navak Guggul in the Management of sthoulya?

OBJECTIVE

1. To study the etiopathogenesis of Sthoulya.

2. To study the efficacy of effective than Navak Guggul in the Management of sthoulya.

Sthoulya

Purvarupa of Sthoulya: Purvarupa are the symptoms that appear prior to the complete manifestation of the disease. None of the Ayurvedic texts has described the Purvarupa of Sthoulya. Acharya Charaka, in Nidana Sthana, has mentioned similar pathogenesis of Prameha and Sthoulya, the reason being that in both there is vitiation of Kapha and Meda. Therefore, Purvarupa of Prameha and Medovaha Srotodushti Lakshanas can be considered as Purvarupa of Sthoulya.

1. Atinidra

- 2. Tandra
- Alasya
- 4. Vistra sharir gandha
- 5. Anga gaurava
- 6. Anga saithilya
- 7. Atisweda etc.

According to Madhavnidan, in Purvarupavastha, increase in Medo Dhatu is observed especially at the abdominal area. This is due to increase in Kapha Dosha and Meda Dhatu which is in the initial stage in Samprapti.

Rupa / Lakshana of Sthoulya

Charaka:

The feature that is present after the complete manifestation of a disorder is known as rupa of that particular disease. Maharshi Charaka has enlisted some cardinal features or pratyatma lakshanas50of Sthoulya that are as follows: -

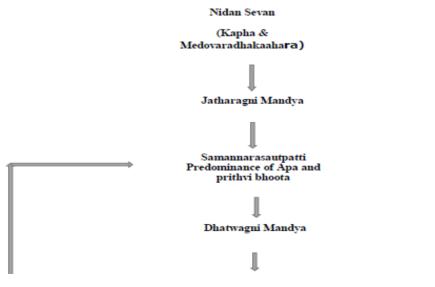
- 1. Medomamsa ativriddhi
- 2. Chala sphika (Pendulous movement of buttock)
- 3. Chala udara (Pendulous movement of abdomen)
- 4. Chala stana (Pendulous movement of breast)
- 5. Ayatha Upachaya (Disproportionate body)
- 6. Anutsaha (Lack of Enthusiasm)

Besides these cardinal symptoms, Acharya Charaka in Sutrasthana has mentioned eight disabilities or Ashta doshas of atisthoola purushas, which are as follows.

The 8 main symptoms (RUPA) of Obesity

- Ayushorhas- Reduced life span
- Javoparodha- Early signs of senility
- Kruchravyavayata- Difficulty in sexual intercourse
- Daurbalya- Fatigue
- Daurgandhya- Foul body odour
- Swedabadh- Excessive perspiration
- Atiksudha- Increase in hunger
- Atitrushna- Increase in thirst.

Flow chart No.1: Sthoulya samprapti



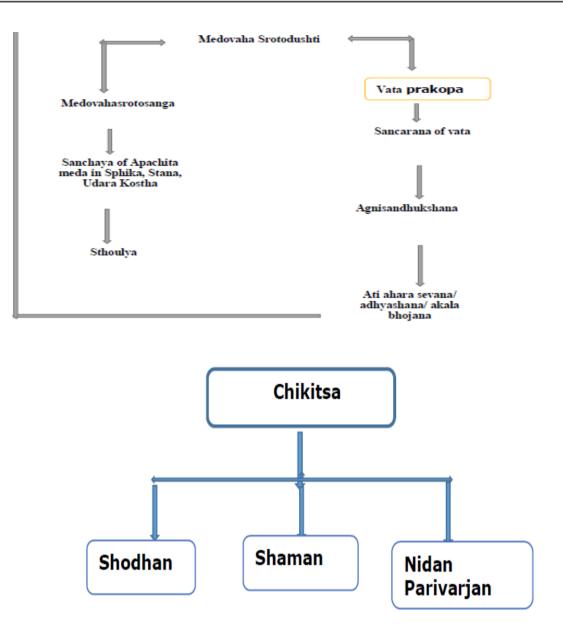


Table No. 8: Methods sanshodhan therapy in Sthoulya

Bahir ParijamanChikitsa	AbhyantaraSamshodhan
1. Udvartana	1. Vamana
2. Avagaha	2. Virechana
3. Parisheka	3. Nasya
4. Lepa	4. Niruha basti

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Vidangadi Lauha

DRAVYA /L.NPRYOJYE ANGRASAVIRYAVIPAKADOSHA NATAVIDANGA (EMBELIA RIBES)PHALAKatu, kashayUshnakatuKapha shamaAMALAKI (EMBELIA OFFICINAL -IS)PHALAPanchras (lavan varjeet)SheetmadhurBIBHITAKI (TER-PHALAKashayUshnamadhur	vaat ka
VIDANGA (EMBELIA RIBES)PHALAKatu, kashayUshnakatuKapha 	ka
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induitat hashay oshina hidanar	
induitat hashay oshina hidanar	
MINALIA	
BELLIRICA)	
HARITAKI PHALA Panchras Ushna madhur	
(TER- MINALIA	
CHEBUL) varjeet) Tridosh	hhar
MUSTA KAAND Tikta,katu, Sheet katu Kapha	
(CYPER kashay pitta	
ROUTODS) shama	ka
PIPALI PHALA, Katu Anuushna madhur Vaat	
(PIPER MOOL sheet shama	ka
LONGUM)	
NAAGER KAAND Katu Ushna katu Kapha	
(ZINGIBER shama	
OFFICINAL	NG
-E)	
BILWE Kashay, Ushna Katu Kapha (AEGEL MOOL tikta	
MADMELO MOOL, UKta	ka
S)	
CHANDAN Tikata, Sheet Katu Kapha (SANTALU-KAAND madhur bitta	
M Price	
ALBUM) shama	ка
HIBAER Katu,tikta Ushna Katu Kapha	T
(JUNIPERU PHAL Vaat	
COMMUNI- CS) shama	ka
PATHA Tikta Ushna katu	
(CISSAMP- MOOL, Tridost	hhar
ELOS	
PAREIRA)	
USHEER Tikta, Sheet katu Kapha	
-IA MOOL madhur pitta	
ZIZANIOID) shama	ka
BALAA madhur Sheet madhur Vaat pi	itta
(SIDA MOOL shama	
CORDIFOLI	
-A)	

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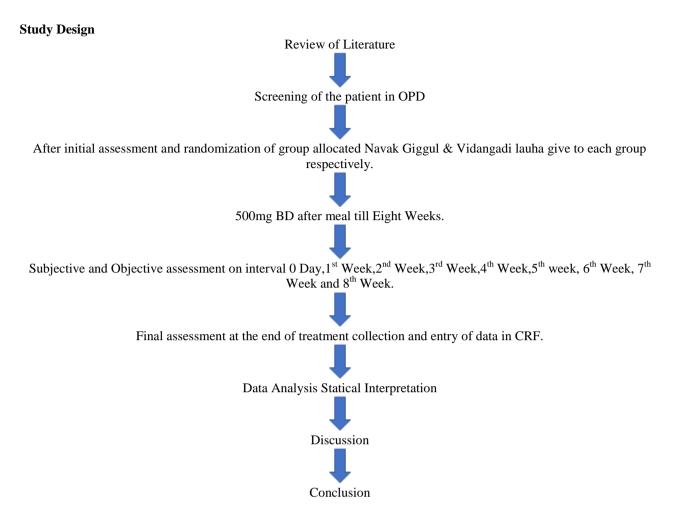
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Navak Guguul

DRAVYA/ L.N	PRAYOJ ANG	RAS	VIRYA	VIPAK	DOSHGH NATA
VAIVIDANG (EMBELIA RIBES)	PHALA	Katu , kashay	Ushna	katu	Kapha vaat shamaka
KALIMIRCH (PIPER NIGRUM)	PHALA	Katu	ushna	katu	Vaat kapha shamaka
PIPALI (PIPER LONGUM)	PHALA, MOOL	Katu	Anuusna sheet	madhur	Vaat shamaka
MUSTAK (CYPERUS ROUTOUND -S)	KAAND	Tikta, katu, kashay	Sheet	katu	Kapha pitta shamaka
CHITRAK MOOL (PLUMBAG ZEYLANICA)	MOOL	Katu	ushna	katu	Kapha vaat shamaka
HARITAKI (TERMINALI -A CHEBULA)	PHALA	Panchras (lavan varjeet)	ushna	madhur	Tridosh har
BIBHITAKİ (TERMINALI -A BELLIRICA)	PHALA	Kashay	ushna	madhur	Tridosh har
AMALAKI (EMBLICA OFFICINALIS	PHALA	Panchras (lavan varjeet)	Sheet	madhur	Tridosh har
SUDHA GUGGUAL (COMIPHOR -A MUKUL)	NIRYAS	Tikta, katu	ushna	katu	Tridosh har
EARAND RICINUS COMMUNIS	MOOL	Madhur, katu, kashay	ushna	madhur	Kapha vaat shamaka

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Criteria of Assessment

Criteria of assessment to evaluate to efficacy of Navak guggul and Vidangadi lauha in the management of sthaulya are divide into following parameters.

INCLUSION CRITERIA

- Irrespective of gender
- Patient with BMI ranging between 25-40
- Patient with classical symptoms of sthaulya roga mentioned in
- Ayurveda texts.
- Age-18-80years
- Religion-no barrier
- Economic status no barrier

EXCLUSION CRITERIA-

- Patient having cardiac disorders, known history of tuberculosis HIV, HBsAg, Hepatitis infectious disease or any other major illness.
- Pregnant and lactating mothers.
- Patient with BMI > 40.
- Pathology induced.

CRITERIA OF WITHDRAWAL

- Any adverse drug reaction seen in patients.
- Discontinuation of the treatment during trial.
- Discharge against medical advice (DAMA)

IAGNOSTIC CRITERIA

- BMI more than 25
- Kshudra swasa / AlpaSwasa
- Alasya / Utsahahani
- Daurbalya/Alpa vyayama
- Chala shipka, sthana, udar lambanam

CRITERIA FOR ASSESSMENT

Assessment was based on the subjective and objective parameters.

SUBJECTIVE PARAMETERS

- Atikshuda.
- Atipipasa.
- Atisweda.
- Ati-nidra.
- Kshudra swasa / AlpaSwasa
- Alasya / Utsahahani
- Daurbalya/Alpa vyayama
- Daurgandhya

OBJECTIVE PARAMETERS

- Weight
- BMI
- Waist hip ratio
- Waist circumference
- Mid arm circumference

• Lipid profile (before treatment and after treatment).

Routine Investigations

- 1. FBS, PPBS
- 2. T3 T4 TSH
- 3. LIPID PROFILE

Investigations before starting the medication.

Tests will be done before treatment so as to exclude other complications and criteria.

OBSERVATION AND RESULT

Research Methodology

In this study, to test the statistical significance of Vidangadi Lauha & Navak Guggul in comparative study in the management of Sthoulya, Clinical study was conducted in total 60 subjects. The subjects were enrolled in the study by confirming their inclusion and exclusion criteria. In this report all quantitative variables are presented using description statistics like mean, mode, median, SD and same is presented using graph and chart. Similarly, all qualitative variables are summarized with count and percentage.

Our Statics Observation for Group A are following

T-Test: Paired Two Sample for Means

Statistical analysis

Data was collected before, during and after the treatment. These were analyzed by using descriptive statistics, contingency table analysis.

We did deep down study on both Vidangadi Lauha & Navak Guggul action on patients. We created Group of 30 patient for each medicine and try to analysis for better understanding.

Group A : Vidangadi Lauha (30 Patients)

Group B : Navak Guggul (30 Patinets)

As per Research Question we need to find: Whether VidangadiLauha is more effective than Navak Guggul in the management of sthoulya?.

Hypothesis

Null Hypothesis H₀**:** Vidangadi lauha is less effective than navak Guggul in the management of sthaulya.

Alternative Hypothesis H_1 : Vidangadi lauha is more effective than navak guggul in the management of sthaulya.

	Variable 1	Variable 2
Mean	78.4666667	73.6
Variance	42.1885057	52.93793103
Observations	30	30
Pearson Correlation	0.88624689	
Hypothesized Mean Difference	0	
df	29	
t Stat	7.9083428	
P(T<=t) one-tail	5.0547E-09	
t Critical one-tail	1.69912703	
P(T<=t) two-tail	1.0109E-08	
t Critical two-tail	2.04522964	

P-Value: 1.0109 $*E^{(-08)}$ is very near to zero . So, it's very less then significance value 0.05.

Observation for Group B are following

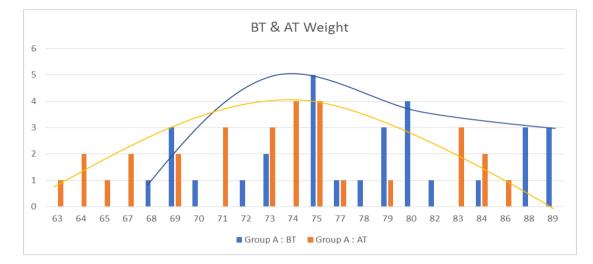
t-Test: Paired Two Sample for M	Ieans	
	Variable 1	Variable 2
Mean	87.48275862	77.96551724
Variance	55.54433498	90.32019704
Observations	29	29
Pearson Correlation	0.875588644	
Hypothesized Mean Difference	0	
df	28	
t Stat	10.96939626	
P(T<=t) one-tail	6.00724E-12	
t Critical one-tail	1.701130934	
P(T<=t) two-tail	1.20145E-11	
t Critical two-tail	2.048407142	

P-Value: 1.020145 *E^(-11) is very near to zero . So, it's very less then significance value 0.05.

As per the observation we can observe that both medicine is significant in management of obesity. As Per

subjective and routine parameter we find out significance difference before and after the treatment. Both Medicine

worked quite well over maximum subject but not all subjects shown significant improvent over the WEIGHT as well as BMI. Here below, we maintioned the findings after the detailed compertaive study of viddhangi Lauha (Group A) and Navak Guggul (Group B).

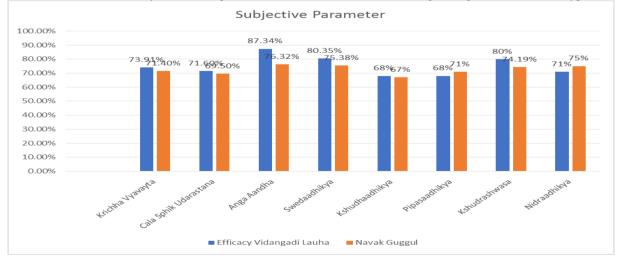


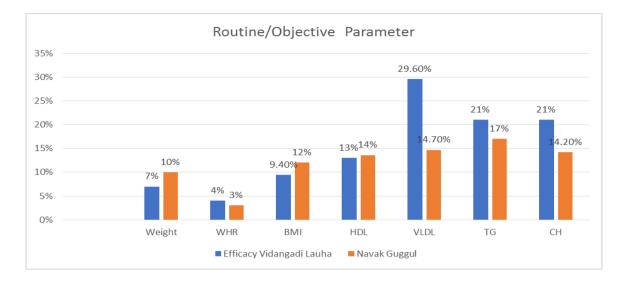
• Average Difference in Weight for Group A is 4.8Kg before treatment and after treatment.

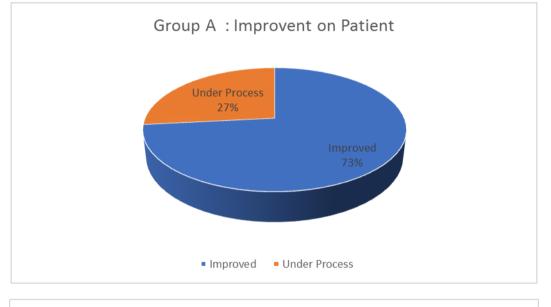


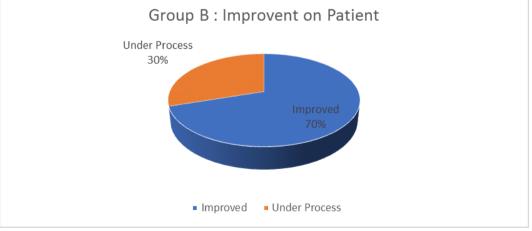
• Average Difference in Weight for Group B is 9 Kg before treatment and after treatment.

Here now we consider efficacy of both drug which make us clear confusion among the significance of null hypothesis









As per above subjective and routine parameter, it's very clear that Vidangadi Lauha is quite efficent then Navak Guggul. Improvement also shows that every subject is under improventment but under 56 days of study vidangadi Lauha shows better result. Stats and parameter of patient clearly shows that Vidangadi Lauha shows better result then Navak Guggul.

DISCUSSION

Discussion is the process of talking about something in order to conclude or exchange ideas. Before establishment of genuineness or truth as conclusion, discussion is obligatory process. Truth should be acknowledged with the logical interpretation. Discussion on the study is being done under the following headings.

- A. Discussion on Observation
- B. Discussion on Results
- C. Discussion on clinical study
- D. Discussion on Probable mode of action of the drugs.

DISCUSSION ON OBSERVATION

Observation findings in our study are of 60 patients. Attempt has been made to discuss on the findings spite of small sample size.

Age- As present study shows there was involvement of subjects of multiple age group. Consumption of fat rich food (Junk food), irregular diet habits, lack of exercise and mental stability comes after settlement in middle age may be the reason behind this.

Religion- Maximum patient of Hindu community observed in this study. This may be due to geographical dominance by particular community, where the study has been carried out and due to small sample study, we cannot conclude, that this disease is more prone in Hindu community. Religion wise variation in number of cases is due to their living and food habitat.

Gender- Incidence of Obesity is slightly more in females than male, our clinical study supports this fact. Females naturally have more adiposity so they are predisposed to obesity. Moreover, there are 3 important phases in female life when they undergo enormous hormonal change, they are menarche, pregnancy and menopause. These changes also contribute to weight gain. Females are also more conscious about their appearance; hence more female are may be observed in my study.

Marital status- After marriage many persons puts on weight is a general observation, there is no textual reference for this weight gain. To draw any conclusion with scientific reason in such condition is very difficult. Sedentary life style and some psychological factors etc. may have important role in this.

Occupation- Maximum subjects in this study was working profile. This can be attributed to the fact that the occupational status of a person determines his/her life style. In urban setup now a days housewives are making use of electronic machines and gadgets for most of the household works due to which the physical activity is minimized. Similar in the case of businessmen and office workers who are mentally more active than physically.

Dietary status- Non vegetarian diet has high calorific value which contributes to the increase in weight, but it can't be concluded that only mixed diet is cause of obesity because the expenditure of calories by exercise is proportionally required to maintain the energy balance. A vegetarian who is physically inactive is equally prone for gaining weight as physically active non vegetarian.

Nidra- Quality of sleep various according to *Dehaprakruti*. Most of the subject in this study has *Kaphaja* and *Kaphanubandhi prakruti*. *Kapha Dosha* is supposed to be composed of mostly *tamasa guna*. Whenever *Chetanasthanam* get covered by the accumulation of *Tamasa guna*, the sensory channels get blocked by the *Kapha Dosha*. When this *Shleshma* is over saturated by *Tamoguna* then the sleep occurs.

Vyayam- Due to lack of exercise, the energy provided by the consumed food is not used, and the extra energy consume is stored by the body as fat.

Divaswap- Sleeping in daytime except in *Greeshma Ritu* causes vitiation of *Kapha* and *Pitta*.

Addiction- 50% subjects in this study had no habits. Consumption of excessive beverages like tea, coffee etc yields extra calories. But in this study this fact can't be proved because of small sample size.

Koshtha- In normal condition, Madhyama kostha found due to kapha dominance. subjects in this study were having Madhyam koshtha. The vitiation of Vata, due to the obstruction of the Strotas, can be considered as the reason behind the incidence of Kroora Koshtha in subjects. In some Mrudu koshthi subjects Dravamala pravrutti was seen during intervention.

Agni- Agni is very important in the *Samprapti* of *Sthoulya*. *Vata*(*Saman vayu*) has been described in the state of *Avrita* in *Kostha* due to *Kapha Dosha*, which makes the *Agnivaishamya*.

DISCUSSION ON RESULTS

Atishudha

In the *Samprapati* of *Sthoulya*, *Vata* (*Saman vayu*) has been described in the state of *Avrita* in *Kostha*, which makes the *Agnivaishamya*, ultimately increases the *Atishudha*(demand of food).

Atipipasa

Due to movement of aggravated *Vata dosha* in *kostha*, it is confined to *Kostha* resulting in the simulation of *Agni* (digestive fire). It is due this *Tikshnagni* the patient drinks water frequently.

Atinidra

In *Sthoulya* there is increase in the *Kapha* which leads to *Tamoguna vriddhi* and ultimately to *Nidradhikya*.

Atisweda

Medoroga is a Meda Vrudhijanya vyadhi and as Sweda is a mala of Meda Dhatu, there is increase in Sweda Pravruti.

Kshudra Swasa

Dyspnea on exertion is caused due to aggravation of Vata and Kapha. There is also decrease in the

contraction and relaxation of diaphragm due to fat deposition in the abdomen.

Alasya/Utshanahani

In *Sthoulya* there is formation of *Ama* and *Kapha vriddhi* which leads to increase *Tamoguna* and thus causes *Alasya*.

Daurbalaya

Daurbalaya is caused by improper nourishment of Dhatu. Guduchyadi Guggulu kashaya leads to Agnivardhan and Amapachaka.

Daurgandhya

Daurgandhya is due to *Medodushti* as *Sweda* is produced from *Meda dhatu*. When *Sweda* mixes with the *kapha*, it results into foul odour. Navak Guggul and Vidangadi lauha helped reduction in Daurgandhya.

Weight and BMI

Navak Guggul and Vidangadi lauha helped reduction in weight and maintain BMI.

Lipid Profile

According to Ayurveda, cholesterol imbalance is caused due to the imbalance in digestion, assimilation and elimination processes. The imbalances in the *Meda dhatu* results in accumulation of bad cholesterol in the body. So, *Meda dhatu* needs to be balance. Navak Guggul and Vidangadi lauha helped to improve lapid profile. Because of that it is helpful to maintain the level of cholesterol. This all helps in significant result in lowering serum LDL, VLDL and increases HDL.

Future Scope

1. Shamana chikitsa is mainly concerned with the Shamana of the Doshas in the body. Although it is effective, but results are very promising if it is used along with some Bahirparimarjana Chikitsa like Udavartana etc for the management of Sthoulya.

2. Sodhana chikitsa is a key tool of treatment in Ayurveda which can also play a vital role in the treatment of *Sthoulya*. A number of therapies like *Lekhana Bastis* etc have been mentioned for the same.

- 3. A well designed Protocol will be more useful.
- 4. Shaman Chikitsa with Aahar Matra Niyojana.

CONCLUSION

Prospective clinical study was conducted on 60 subjects who were assessed for 56 days. On the basis of the observations made in clinical study, following conclusions were drawn.

- In this there was involvement of subjects of multiple age group. Among these younger adults and adults were affected in larger scale.
- Incidence of Obesity is slightly more in females than male, our clinical study supports this fact.
- As per this study *Sthoulya* is common in married, Educated and upper- and middle-class people. Subjects having sedentary lifestyle and housewives.

- The drug used in this study has very good result in subjective parameters. As excellent result.
- Average 5 kg weight loss is observed in the subjects enrolled in this study which is significant result.
- The mean of BMI reduced by3 to 4 which is significant.
- ✤ Overall result was statistically highly significant with 'P' <0.05.</p>

The promising results of the improvement in symptoms of *Sthoulya* with none of the side effects, prove its curative efficacy and provide new ground for the further research on large.

1. Shamana chikitsa is mainly concerned with the Shamana of the Doshas in the body. Although it is effective, but results are very promising if it is used along with some Bahirparimarjana Chikitsa like Udavartana etc for the management of Sthoulya.

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- 3. A well designed Protocol will be more useful.
- 4. Shaman Chikitsa with Aahar Matra Niyojana.

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