

**A RANDOMISED CONTROL COMPARATIVE, PHASE II , CLINICAL  
STUDY OF STHAULYA (OBESITY) WITH SHADUSHAN GUGGULU  
WITH SPECIAL REFERENCE TO HYPERLIPIDEMIA**

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**ABSTRACT:**

Obesity is a natural consequence of over nutrition and sedentary lifestyle. Environmental and behavioural changes brought about by economic development, modernization and urbanization has been linked to the rise in prevalence of lifestyle related disorders like Obesity. Obesity is an epidemic of the 21st century. WHO identifies main global leading risks factors causing today's diseases, disability and deaths. Out of which, Overweight is one of the top ten causes of death throughout the world. In modern medical science, management of obesity remains symptomatic with troublesome side effects. In this situation, Ayurveda has many positive and successful treatment modalities for Sthaulya. All the ingredients of 'Shadushan' are Katu-Tikta Rasatmak, Katu Vipaki, and Ushna Viryatmak. So, to break pathogenesis of Sthaulya 'Shadushan Gaggulu' as experimental drug and 'Shudha Guggulu' as control group have been selected. For present clinical trial total 60 patients were selected and randomly divided into two groups. On statistical analysis significant result has been found in subjective and objective parameters of both groups. On comparative study both the treatment procedures found to be equally effective.

**KEYWORDS:** *Shadushan Guggulu , Sthaulya , obesity*

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## Introduction:

Obesity is a natural consequence of over nutrition and sedentary lifestyle. Environmental and behavioural changes brought about by economic development, modernization and urbanization has been linked to the rise in prevalence of lifestyle related disorders like Obesity. Obesity is an epidemic of the 21st century. WHO identifies main global leading risks factors causing today's diseases, disability and deaths. Out of which, Overweight is one of the top ten causes of death throughout the world. Obesity is mainly due to the imbalance of high energy input through rich foods and low energy expenditure due to lack of physical exercise. The risk of cardiovascular diseases (CVDs), hypertension, hyperlipidemia, diabetes mellitus, and certain cancers increases many folds in association with obesity.

Hyperlipidemia is one such condition where the direct reference is not mentioned in any of the *Ayurvedic* classical texts. *Acharya Charaka* has thrown light on the eight varieties of impediments which are designated as *Nindita Purusha*. *Atisthaulya* comprises one of them. In *Ayurvedic* system of medicine, Hyperlipidemia can be considered under the title of '*Medoroga*' which stands amongst '*Asta Ninditiya Roga*' as "*Sthaulya Roga*" in *Charaka Samhita*.

In modern medical science, management of obesity remains symptomatic with troublesome side effects. In this situation, *Ayurveda* has many positive and successful treatment modalities for *Sthaulya*. The management of *Sthaulya* is so scientific and contemporary, that there is always a wide scope of research in *Ayurveda*. Till now, lot of research work has been done to overcome *Sthaulya*, mainly with Panchakarma procedures including *Lekhan Basti*, *Virechan* and various types of Guggulu and significant results have been observed.

In the pathology of *Sthaulya*, *Kapha* is main *Dosha* and *Meda* is main *Dushya*, while *Agnimandya* takes place at *Medodhatvagni* level. So that ideal drug therapy to be selected should have *Kapha-Medanashaka* property and efficacy to correct the function of *Medodhatvagnimandya*. All the ingredients of '*Shadushan*' are *Katu-Tikta Rasatmak*, *Katu Vipaki*, and *Ushna Viryatmak*. So, to break pathogenesis of *Sthaulya* '*Shadushan Gaggulu*' as experimental drug and '*Shudha Guggulu*' as control group have been selected. Total 60 patients were selected for this clinical study. These 60 patients were randomly divided into two groups.

Hence the present research work is undertaken to study ‘The effect of *Shadushan Guggulu* in the management of *Sthaulya* (Obesity) with special reference to hyperlipidemia.’

#### **AIMS AND OBJECTIVES :**

1. To assess the clinical efficacy of Shadushan Guggulu on different parameters of Sthaulya (Obesity).
2. To assess the clinical efficacy of Shadushan Guggulu on hyperlipidemia.

#### **HYPOTHESIS OF THE STUDY :**

**H<sub>0</sub>** : The clinical efficacy of Shadushan Guggulu on different parameters of Sthaulya (Obesity) is more significant effect than Shudha Guggulu.

**H<sub>1</sub>** : The clinical efficacy of Shadushan Guggulu on different parameters of Sthaulya (Obesity) is equally significant effect with Shudha Guggulu.

#### **MATERIAL AND METHODS**

**SOURCE OF DATA:** Patients who were attending the O.P.D and I.P.D of Kayachikitsa Department of Ayurveda Rugnalaya fulfilling the criteria were selected for the study.

**CRITERIA FOR INCLUSION:** The obese patients who were having BMI > 25 and increased lipid profile in the age group of 16-60 years were selected irrespective of their sex from Kayachikitsa O.P.D and I.P.D Ayurveda Rugnalaya. Clinical history of patients was taken in special prepared proforma.

#### **CRITERIA OF EXCLUSION:-**

- 1) Age below 16 years and above 60 years.
- 2) Any endocrinological disorders.
- 3) Patients having any severe systemic disorder Such as DM/ HTN/ TB/Asthma/Chronic renal disorder.
- 4) Pregnant women.
- 5) Patients who have BMI>40

#### **Subjective Parameters :-**

1. *Alasya / Utsahahani*

2. *Kshudraswasa (Dyspnoea on exertion)*

- |                                     |                                    |
|-------------------------------------|------------------------------------|
| 3. Daurbalya (Generalised weakness) | 4.Swedadhikya (Excessive sweating) |
| 5. AngaGaurava (Heaviness of body)  | 6.Atikshudha (Excessive hunger)    |
| 7. Atipipasa (Excessive thirst)     | 8 .Sandhishoola(Joint pain)        |

### **Objective Parameters:-**

#### **1. Skin fold thickness:**

The width of subcutaneous skinfold in the region of

- Triceps was measured with calibrated callipers.

>23m.m in males (over the triceps indicate obesity)

>30m.m in females (over the triceps indicate obesity)

#### **2 .Waist circumference:**

Waist circumference> 102 cm for males.

Waist circumference> 88 cm for females.

#### **3.BMI:**

The patients who were having BMI above 25 (Kg/m<sup>2</sup>) were selected.

BMI = Body weight(Kg)/ Height (m<sup>2</sup>)

### **Laboratoy Parameters:-**

**A.Blood:** Hb %, TLC, DLC, ESR.,BSL Fasting & Post prandial,Lipid profile

(Total cholesterol, Serum triglyceride,HDL,LDL)

**B.Urine:** Routine

Microscopic

### **Drug Review:-**

#### **Group A-Shadushan Guggulu**

The all ingredients of Shadushan Guggulu were taken in equal quantity and pounded well so as to prepare Shadushan Guggulu as per the reference mentioned in Bharat Bhaishajya Ratnakara in pharmacy of Ayurveda Mahavidyalaya . 500 mg tablets of Shadushan Guggulu were prepared.

#### **Group B-Shudha Guggulu :**

Guggulu Shodhan was done in Triphala kwath. Triphala kwath was prepared as per standard procedure of Kwath preparation as mentioned by Acharya Sharangdhara<sup>6</sup>. After complete drying, 500 mg tables of Shudha Guggulu were prepared.

## **RESEARCH METHODOLOGY:**

After doing complete examination and investigations, the patients selected for research trial were randomly divided into two groups. The drug was administrated after 'Sharira Shudhi' i.e. the patients of both the groups were subjected to Bashpa Sweda for 5 days and Anuloman with Erandasneha, on the 6<sup>th</sup> day.

### **Group A Experimental Group-**

In this group 30 patients were kept on Shadushan Guggulu in 500mg dose TID in empty stomach with lukewarm water for 90 days.

### **Group B Control Group-**

In this group 30 patients were kept on Shudha Guggulu in 500 mg dose TID in empty stomach with lukewarm water for 90 days.

### **Restricted Diet:-**

During the treatment period, the patients were advised to follow some dietic principles and normal diet was advised. Diet card was provided to each patient. Emphasis was given on Guru and Apatarpan Ahar.

### **Advised Vihar and Exercise :-**

Regulating bowel movements, avoiding diwaswap, avoiding luxurious habits were advised. Daily 1/2 hrs Walking exercise was advised.

## **CRITERIA FOR ASSESSMENT:-**

The patients subjected to clinical trials were observed for improvement biweekly intervals for the duration of three months. The subjective and objective parameters were assessed biweekly. And the laboratory parameters were assessed before and after the treatment. Improvement was assessed on the basis of percentage relief.

### **CRITERIA FOR ASSESSMENT:-**

Reduction in body weight 10 percent.

Reduction in BMI ratio 10 percent.

Reduction in body circumference & skin fold thickness 10 percent.

Improvement in Haematological Parameter 10 percent.

Improvement in signs and symptoms 60 percent.

**OVERALL THE EFFECT OF THERAPY WILL BE ASSESSED AS :**

1. Excellent improvement : > 75% relief.
2. Marked improvement : 50% to 74.9% relief.
3. Moderate improvement : 25% to 49.9% relief.
4. Mild Improvement : < 24.9% relief.

**OBSERVATIONS AND RESULTS**

**Data Analysis:**

**Table No 5.1:**

**Age Wise distribution of Sthaulya patients**

Age	Group A		Group B		Total	
	No. of Patient	Percentage	No. of Patient	Percentage	No. of Patient	Percentage
15-25	03	10	05	16.67	08	13.33
26-35	02	6.67	07	23.33	09	15
36-45	04	13.33	06	20	10	16.67
46-55	08	26.67	07	23.33	15	25
55-65	13	43.33	05	16.67	18	30

(Source:Primary Data)

In present clinical study, most of patients were from 55-65 age group (30 percent). Followed by 46-55 age group (25 percent), 36-45 age group (16.66 percent),26-35 age group (15 percent) and 15-25 age group (13.33 percent).

**Table 5.2:**

**Sex Wise distribution of Sthaulya patients:**

Sr. No.	Sex	Group A		Group B		Total	
		No. of Patient	Percentage	No. of Patient	Percentage	No. of Patient	Percentage
1	Male	06	20	09	30	15	25
2	Female	24	80	21	70	45	75

(Source:Primary Data)

In this study, maximum patients were female 75 percent, where as male patients were 25 percent.

**Table 5.3:**

**Family History Wise distribution of Sthaulya patients**

Sr. No.	Family History	Group A		Group B		Total	
		No. of Patient	Percentage	No. of Patient	Percentage	No. of Patient	percentage
1	Yes	24	80	23	76.67	47	78.33
2	No.	06	20	07	23.33	13	21.67

(Source:Primary Data)

Maximum patients of this study 78.33 percent reported positive family history of Obesity, where as 21.67 percent patients were observed with negative family history.

**Table 5.4:**

**Diet Wise distribution of Sthaulya patients**

Sr. No.	Diet	Group A		Group B		Total	
		No. of Patient	Percentage	No. of Patient	Percentage	No. of Patient	Percentage
1	Veg	18	60	13	43.33	31	51.67
2	Mixed	12	40	17	56.67	29	48.33

(Source:Primary Data)

In present clinical study, 51.67 percent of patients were vegetarian, where as 48.33 percent of patients were consuming non veg diet.

**Table 5.5:**

**Testing of hypothesis On Mean Gradation Of Symptoms Of Sthaulya In Group A and Group B**

Sr.No	Subjective para.	Group A				Group B			
		MR	S.E	t cal	Percentage	MR	S.E	t cal	Percentage
1	Alasya/ Utsahahani	2.03	0.05	34.83	66	2.13	0.07	26.92	68.08
2	Kshudra Swasa	2.5	0.11	21.75	70.75	2.8	0.1	27.85	73.04
3	Daurbalya	2.6	0.12	21.11	69.64	2.9	0.08	33.06	73.72
4	Swedadhikya	2.61	0.12	18.33	57.01	2.1	0.09	21.01	53.85
5	AngaGaurav	2.56	0.13	19.32	70	2.86	0.07	36.18	73.50
6	Atikshudha	1.2	0.1	11.93	42.35	1.4	0.10	13.62	45.16
7	Atipipasa	1.2	0.1	11.93	49.31	1.56	0.10	13.62	54.02
8	Sandhisool	2.5	0.16	15.21	68.80	2.46	0.12	13.62	66.67

(Source:Primary Data)



**Table. 5.6: Effect Of Treatment On Mean Gradation Of Objective Parameters In Group A and Group B:**

Sr.No	Parameters	Group A			Group B	
		Statistical Parameters	BT	AT	BT	AT
1	Weight	AM	72.6	68.66	78.56	74.7
		SD	9.419	9.113	12.161	12.202
		SE	1.718	1.663	2.21	2.226
2	BMI	AM	30.08	28.45	31.077	29.57
		SD	3.45	3.338	3.657	3.702
		SE	0.629	0.609	0.667	0.675
3	Waist	AM	118.23	116.53	118.1	116.95
		SD	10.679	10.234	8.586	8.444
		SE	1.948	1.867	1.566	1.541
4	Hip	AM	115.73	114.3	112.05	111
		SD	7.597	7.273	7.714	7.683
		SE	1.386	1.327	1.407	1.402
5	WHR	AM	1.0242	1.0222	1.0563	1.0561
		SD	0.0971	0.0961	0.0745	0.0755
		SE	0.0177	0.0175	0.0136	0.0137
6	Skinfold	AM	33.89	31.61	34.176	33.1
		SD	4.736	7.065	5.146	5.174
		SE	0.864	1.289	0.939	0.944

(Source:Primary Data)

**Table 5.7:**

**Testing of hypothesis on Objective parameters between first and last day under study:**

Parameters	Group A				Group B			
	MR	S.E	t cal	Percentage	MR	S.E	t cal	Percentage
Weight	3.933	0.208	18.863	5.42	3.867	0.149	25.862	4.92
BMI	1.631	0.089	18.293	5.42	1.506	0.072	20.871	4.84
Waist	1.7	0.192	8.82	1.44	1.15	0.064	17.94	0.97
HIP	1.43	0.132	10.79	1.23	1.05	0.064	16.16	0.93
WHR	0.002	0.0016	1.25	0.19	0.0002	0.0008	0.309	0.02
Skin fold Thickness	1.516	0.11	13.66	4.47	1.073	0.038	27.79	3.14

(Source:Primary Data)

The mean reduction in Weight between 1<sup>st</sup> and 90<sup>th</sup> day was 3.93 with 5.42% relief in group A and 3.87 with 4.92% relief in group B was observed. In BMI also, mean reduction 1.63 with 5.42% in group A and 1.50 with 4.84% relief in group B was observed. All the results were statistically highly significant. The effect on Waist and Hip measurement was shown in table indicates that, Statistically highly significant relief was found in both the group A and group B. No significant result was found in WHR in both the groups. Decrease in Waist measurement by 1.44% in group A, 0.975 in group B and in Hip measurement by 1.23% in group A, 0,93% in group B. The mean reduction in Skin fold thickness 1.51 with 4.47% relief in group A and 1.07 with 3.14% relief in group B was observed.

**Table 5.8:**

**Effect of treatment on mean gradation of Lipid Profile in Group A and group B**

Sr. No.	Parameters	Statistical Parameter	Group A		Group B	
			BT	AT	BT	AT
1	Total Cholesterol	AM	217.99	168.96	182.7	171.5
		SD	34.71	22.69	26.156	18.15
		SE	6.33	4.14	4.773	3.312
2	Serum Triglycerides	AM	173.66	126.54	182.43	147.73
		SD	45.213	21.98	36.521	31.131
		SE	8.25	4.01	6.664	5.68
3	LDL Cholesterol	AM	145.84	98.7	129.11	101.52
		SD	36.229	21.64	37.626	21.331
		SE	6.611	3.95	6.866	3.892
4	HDL Cholesterol	AM	44.89	38.53	39.84	41.246
		SD	12.992	3.714	11.822	2.597
		SE	2.37	0.677	2.157	0.473
5	LDL/HDL Ratio	AM	3.495	2.611	3.439	2.476
		SD	1.193	0.679	1.263	0.59
		SE	0.217	0.124	0.23	0.107

(Source:Primary Data)

**Table. 5.9:**

**Effect on Lipid profile between first and last day under study.**

Parameters	Group A				Group B			
	MR	S.E	t cal	Percentage	MR	S.E	t cal	Percentage
Tol.Cholesterol	49.03	5.988	8.18	22.49	11.203	3.451	3.24	6.13
S.Triglyceride	47.11	7.594	6.20	27.12	34.7	5.712	6.07	19.02
LDL	47.15	5.430	8.68	32.32	27.59	5.248	5.25	21.36
HDL	6.355	2.340	2.71	14.15	1.405	2.215	0.63	-3.52
LDL/HDL	0.884	0.209	4.22	25.29	0.96	0.200	27.79	27.98

(Source:Primary Data)

The effect on total cholesterol was shown in table indicates that statistically highly significant result was found by 22.49 % in group A and 6.13% in group B.

Statistically highly significant reduction was found in serum triglyceride level by 27.12% in group A and 19.02% in group B.

The LDL level decreased by 32.32% and 21.36% in the group A and group B respectively, were observed statistically significant.

The effect was shown in table indicates that LDL/HDL ratio decreased by 25.29% in group A and 27.98% in group B.

**Table.5.10:**

**Comparison Between Subjective Parameters Of Two Groups:**

Sr.No.	Sypmtoms	Group A		Group B		Combine S.E	Z cal	Decision
		AM1	SD1	AM1	SD1			
1	Alasya/Utsahahani	1.066	0.253	1	0	0.3577	0.1844	Accept
2	Kshudra Swasa	1.033	0.182	1.033	0.182	0.2595	0	Accept
3	Daubalya	1.133	0.345	1.033	0.182	0.4890	0.2044	Accept
4	Swedadhikya	1.633	0.490	1.8	0.406	0.6937	0.2407	Accept
5	Angagaurava	1.1	0.305	1.033	0.182	0.4378	0.1530	Accept
6	Atikshudha	1.633	0.490	1.7	0.534	0.6937	0.0965	Accept
7	Atipipasa	1.23	0.430	1.33	0.479	0.6161	0.1623	Accept
8	Sandhishool	1.13	0.345	1.23	0.430	0.4959	0.2016	Accept
9	BMI	2.8	1.297	3.1	1.470	1.8359	0.1634	Accept

(Source:Primary Data)

**Table.5.11:**

**Comparison between Objective Parameters Of Two Groups:**

Sr.No.	Sypmtoms	Group A		Group B		Combine S.E	Z cal	Decision
		AM1	SD1	AM1	SD1			
1	Weight	68.66	9.113	74.7	12.202	12.890	0.4685	Accept
2	BMI	28.45	3.338	29.570	3.702	5.2362	0.2138	Accept
3	Waist	116.53	10.234	116.95	8.444	4.9742	0.0844	Accept
4	Hip	114.3	7.273	111	7.683	10.4044	0.3171	Accept
5	WHR	1.0222	0.0961	1.0561	0.07553	0.1366	0.2481	Accept
6	Skin fold	31.61	7.065	33.10	5.174	10.092	0.1476	Accept

(Source:Primary Data)

**Table.5.12:**

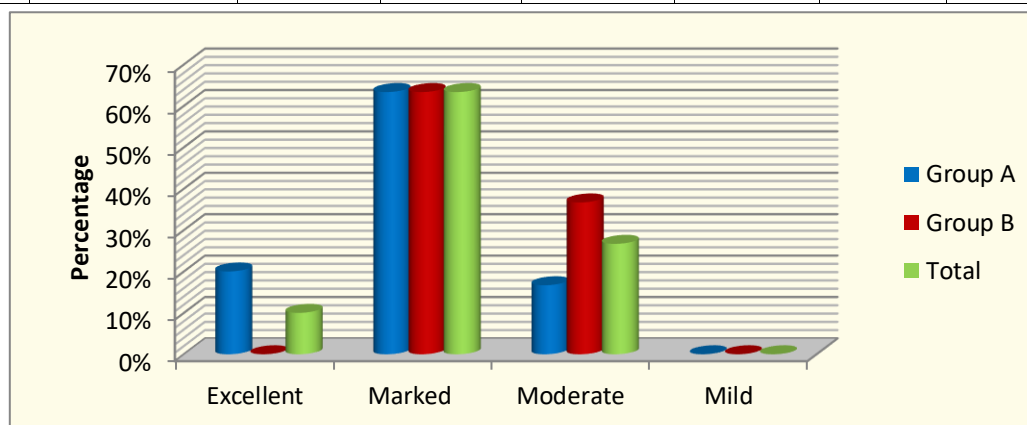
**Comparison between Biochemical Parameters of Two Groups:**

Sr. No.	Sypmtoms	Group A		Group B		Combine S.E	Z cal	Decision
		AM1	SD1	AM1	SD1			
1	Tot. Cholesterol	168.96	22.69	171.5	18.15	32.10	0.0791	Accept
2	Serum Triglyceride	126.54	21.98	147.73	31.13	31.26	1.4379	Reject
3	LDL	98.7	21.64	101.52	21.33	31.14	0.0905	Accept
4	HDL	38.53	3.71	41.24	2.59	6.57	0.4128	Accept
5	LDL/HDL Ratio	2.611	0.67	2.47	0.59	1.07	0.12563	Accept

(Source:Primary Data)

**Table.5.13: OVERALL EFFECT OF THERAPY:**

Sr. No.	Assess-ment	Group A		Group B		Total	
		No. of Patient	Percent	No. of Patient	Percent	No. of Patient	Percent
1	Excellent	06	20	0	0	06	10
2	Marked	19	63.33	19	63.33	38	63.33
3	Moderate	05	16.67	11	36.67	16	26.67
4	Mild	0	0	0	0	0	0



### Overall effect of therapy:

In group A, 20% patients having excellent improvement, 63.33% having marked improvement, 16.67% patients having moderate improvement in all signs and symptoms.

In group B, 63.33% patients having marked improvement, 36.67% patients having moderate improvement in all signs and symptoms.

### DISCUSSION:

In the pathology of *Sthaulya*, *Kapha* is main *Dosha* and *Meda* is main *Dushya*, while *Agnimandya* takes place at *Medodhatvagni* level. So, that ideal drug therapy to be selected should have *Kapha* and *Medanashaka* property and should have efficacy to correct the function of *Medodhatvagnimandya*. So, to break pathogenesis of *Sthaulya* ‘*Shadushan Guggulu*’ and ‘*Shudha Guggulu*’ have been selected.

The *Shadushan Guggulu* contains *Pippali*, *Pippalimula*, *Chavya*, *Chitraka*, *Shunthi*, *Maricha* in equal proportion along with *Guggulu*, *Madhu* and *Ghritra*. All the ingredients of ‘*Shadushan*’ are *Katu-TiktaRasatmak*, *KatuVipaki*, and *UshnaViryatmak* which helps in clearing obstruction in the channels. The combined effect of drug on *Medaroga* may be *Lekhan*, *Vata-Kapha Shaman*, *Deepana-Pachana*; especially on *MedaDhatwagni*. Hypolipidemic and hypocholesteromic effect of *Guggulu* is also proved by various studies.

Present study reveals that the patients got statistically highly significant results in their signs and symptoms in both the groups, Group A ‘*ShadushanGuggulu*’ and Group B ‘*ShudhaGuggulu*’.

In Group A, ‘*ShadushanGuggulu*’ has shown highly significant results in reduction of weight ( $t = 18.86$ ,  $P < 0.001$ ), by 5.42 percent and BMI ( $t = 18.29$ ,  $P < 0.001$ ), by 5.42 percent. In Group A, ‘*ShadushanGuggulu*’ has shown highly significant results in reduction of Total Cholesterol ( $t = 8.18$ ,  $P < 0.001$ ), by 22.49 percent, S. Triglyceride ( $t = 6.20$ ,  $P < 0.001$ ), by 27.12 percent and LDL Cholesterol ( $t = 8.68$ ,  $P < 0.001$ ), by 32.32 percent.

In Group B, ‘*ShudhaGuggulu*’ has shown highly significant results in reduction of weight ( $t = 25.86$ ,  $P < 0.001$ ), by 4.92 percent and BMI ( $t = 20.87$ ,  $P < 0.001$ ), by 4.84 percent. In Group B, ‘*ShudhaGuggulu*’ has shown highly significant results in reduction of Total Cholesterol ( $t =$

3.25,  $P < 0.001$ ), by 6.13 percent, S. Triglyceride ( $t = 6.07$ ,  $P < 0.001$ ), by 19.02 percent and LDL Cholesterol ( $t = 5.25$ ,  $P < 0.001$ ), by 21.36 percent.

While comparing both the groups, the superiority of either of drug in the efficacy cannot be elicited as they are statistically equally effective.

#### **CONCLUSION:**

- The study has been revealed that the prevalence of *Sthaulya* (Obesity) is higher amongst the urban populations especially in women (75 percent) of high socioeconomic class. The rate of obesity also increases with age. In present study it is observed that the prevalence is higher in 46-60yrs age group (55 percent).
- The study reveals that the patients got statistically highly significant results in subjective, subjective and biochemical parameters in both the groups, Group A '*ShadushanGuggulu*' and Group B '*ShudhaGuggulu*'.
- In group A, 20 percent patients had excellent improvement, 63.33 percent got marked improvement, 16.67 percent patients got moderate improvement in all subjective, objective and biochemical parameters.
- In group B, 63.33 percent patients having marked improvement, 36.67 percent patients having moderate improvement in all subjective, objective and biochemical parameters.
- While comparing both the groups, the superiority of either of drug in the efficacy cannot be elicited as they are statistically equally effective.
- As far as the disease chronicity is concerned, for more effective results the treatment duration should be lengthened.



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