

Clinical Efficacy of Apamarga Tandula and Vyoshadi Guggulu on Sthaulya

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Abstract

Sthaulya (Obesity) is a disease which invites many other major and minor diseases. It has turned into a pandemic and needs attention from all, for its control. The present study was done to evaluate the efficacy of trial drugs *Apamarga Tandula* & *Vyoshadi Guggulu* in comparison to standard drug Sibutramine. Sixty subjects were randomly divided in three groups and *Apamarga Tandula* was given to group A, *Apamarga Tandula* & *Vyoshadi Guggulu* was given to group B and the standard drug Sibutramine was given to group C. Patients having clinical presentation of *Sthaulya* as mentioned in the ayurvedic texts (*Prayatma lakshana*) parameters as well as laboratory parameters viz., Hb, TLC, FBS, Cholesterol, TG, HDL, LDL and VLDL, were assessed for its efficacy. The trial groups displayed a comparable result in the laboratory and *Prayatma lakshana* parameters. In variables such as FBS and LDL, the drug *Apamarga Tandula* was found to be better than the control drug. In a display of synergistic action, trial drugs *Apamarga Tandula* + *Vyoshadi Guggulu* showed the best results in all the parameters, much better than the control drug Sibutramine.

Keywords

Sthaulya, Obesity, Laboratory parameters, *Apamarga*, *Vyoshadi guggulu*

INTRODUCTION

Diet and lifestyle are major factors thought to influence susceptibility to many diseases. In many western countries, people began to eat more meat, dairy products, vegetable oils, sugary foods, and alcoholic beverages during the latter half of the 20th century. People also developed sedentary lifestyles and greater rates of obesity [1]. Obesity is one of the highly neglected health problems, which invites many major and minor diseases. Presently obesity has turned into a pandemic and needs attention from all

for its control. WHO further projects that by 2015 approximately 2.3 billion adults will be overweight and more than 700 million will be obese [2].

Non communicable diseases (NCDs), especially cardiovascular disease, cancer and Type 2 diabetes mellitus, account for 53 and 44% of all deaths and disability adjusted life years (DALYs), respectively in India [3]. Prevalence of Obesity and its adverse health effects have risen more rapidly in South Asia, including India. The Nutrition Foundation of India has shown that 32.3%

of middle class males and 50% of middle class females in Delhi are obese. Twenty million Indians are obese and by 2025 the expected number will rise to 68 million [4].

A person is said to be obese when due to excessive growth of flesh and fatty tissues, the hips, abdomen and breasts of the person become bulky and the person suffers from disproportionate metabolism and enthusiasm [5]. *Acharya Sushruta* has exclusively described *Sthaulya*, its etiological factors, patho-physiology, complications as well as the treatment. According to him *Aahar rasa* is the productive cause for both obesity & emaciation [6].

The disease “*Sthaulya*” is as old as the history itself, but it is one of the most neglected health problems since ages, most of the people have not been ready to accept the bitter truth that it is a disease and can lead to grave consequences. Obesity, therefore, needs to be addressed properly by mortality & morbidity.

Aims and Objectives:

To study and compare the efficacy of trial drug “*Apamarga Tandula*” and “*Vyoshadi guggulu*” with that of standard drug “*Sibutramine*” in appetite suppression and weight loss.

MATERIALS AND METHODS

Source of Data:

The study was carried out in OPD & IPD of National Institute of Ayurveda, Jaipur and special camps were conducted by NIA, Jaipur.

Inclusion Criteria:

Adult subjects of age more than 18 years, found to be overweight in present study on the basis of subjective parameters or *Pratyatma lakshana* such as *Chala Udara*, *Gaurava*, *Kshudha* *Vrididhi*, *Ayathaopachaya* etc., were selected for the study. After taking consent to participate in the drug trial and not falling in the exclusion criteria, the studies were conducted.

Exclusion Criteria:

The following criteria was used to exclude patients: hypersensitivity, patients receiving mono amine oxidase inhibitor, anorexia nervosa, history of coronary artery disease, congestive heart failure, stroke, cardiac disorders, depression and pregnancy.

Study Design and Sample Size:

Total sixty overweight subjects in the *Upashayatmaka* study with consent to participate in the drug trial were selected and randomly divided into three groups –

Group A: *Apamarga tandula* powder in dose of 3gm. twice daily, before meals.

Group B: *Vyoshadi Guggulu* in the dose of 500 mg in addition to *Apamarga tandula* powder in dose of 3gm. twice daily, before meals.

Group C: One capsule of Standard Control drug Sibutramine in the dose of 10 mg once daily.

All the patients were advised low calories pathya (compatible/ideal diet plan). No. of dropout cases in Group A, B and C were 4, 6 and 8, respectively. Therefore, no. of analyzed subjects were n=16, 14 and 12 in group A, B and C, respectively.

Selection of drug:

Apamarga Tandula: This drug has been mentioned as appetite suppressant in Ayurvedic texts so to evaluate its action this was taken for the trial ^[7].

Vyoshadi Guggulu: The formulation was selected because as mentioned in its *phalashruti* the formulation reduces the *Meda* (lipids), which is a key ingredient in overweight ^[8].

Standard Drug: The drug of choice for the treatment of Obesity in allopathy is Sibutramine.

Source of formulation:

Ingredient of *Vyoshadi guggulu* viz., one part of each drugs *Shunthi*, *Maricha*, *Pippali*, *Chitraka*, *Mustaka*, *Amalaki*, *Vibhitaki*, *Haritaki*, *Vidanga* and 9 part of *Guggulu* were taken together and made into a *vati* of 250 mg each by standard procedure at the Pharmacy of NIA, Jaipur. The dose of this *Vyoshadi guggulu* was two *vatis* twice

a day before meals thus making the dose 1 gm. per day.

Assessment criteria:

Assessment was done every fifteen days once before the start, during and at the end of the trial however for ease of understanding data of pre-and post-treatment is being presented. After completion of 8 weeks of trial, the effect of therapy was assessed on the basis of following subjective as well as objective criteria. A multidimensional scoring pattern was adopted for the sign and symptoms of *Sthaulya*. The criteria are mentioned in ayurvedic text in subjective or *Pratyatma lakshana* parameters. Laboratory parameters included in objective parameters are history, clinical examination, systemic examination according to specially prepared CRF, incorporating ayurvedic parameters of *Dashavidha Pareeksha*, *Ashta vidha pareeksha* etc. Apart from above parameters WHO STEPs questionnaire etc. were also included in the criteria.

Withdrawal Criteria:

If any patient develops any S/S (sign and symptoms) of adverse reactions or deteriorates, he/she was withdrawn from the trial. Three patients developed S/S of adverse reactions and one patient was found to be pregnant after start of the trial. All

these were withdrawn from the study in the Sibutramine group.

Primary Clinical end point: 5 % reduction in body weight.

Surrogate end points: Improvement in quality of life and biochemical parameters.

Data Documentation and Statistical Analysis:

Data was analyzed using appropriate statistical tests. Unpaired 't' test was used for the parametric data and Wilcoxon rank sum tests for non parametric data as and when applicable.

Table 1 Effect of Trial Drug *Apamarga Tandula* on Laboratory Parameters [Group A; n=16]

Parameters	Mean		Dif.	% of Change	SD	SE	T	P Value
	BT	AT						
HB	13.76	13.72	0.04	0.27	1.04	0.26	0.14	0.8871
TLC	8187.50	9506.25	1318.75	16.11	3291.85	822.96	1.60	0.1299
FBS	103.40	95.18	8.22	7.95	11.51	2.88	2.86	0.012*
Cholesterol	194.58	185.00	9.58	4.92	33.76	8.44	1.14	0.2742
TG	151.66	170.16	18.51	12.20	45.18	11.30	1.64	0.1221
HDL	64.82	60.01	4.81	7.42	20.28	5.07	0.95	0.3576
LDL	101.79	89.53	12.26	12.05	17.76	4.44	2.76	0.0145*
VLDL	30.83	34.19	3.36	10.89	8.96	2.24	1.50	0.1549

BT- Before therapy AT-After Therapy SD-Standard Deviation SE-Standard Error T and p are obtained statistically

Table 2 Effect of Trial Drugs *Apamarga Tandula + Vyoshadi Guggulu* on Laboratory Parameters [Group B; n=14]

Parameter	Mean		Dif.	% of Change	SD	SE	T	P Value
	BT	AT						
HB	13.79	13.58	0.21	1.50	1.00	0.27	0.78	0.451
TLC	8685.71	9100.00	414.29	4.77	2329.03	622.46	0.67	0.5173
FBS	104.29	96.42	7.87	7.54	11.77	3.15	2.50	0.0266*
Cholesterol	190.60	180.01	10.59	5.55	33.80	9.03	1.17	0.2624
TG	149.10	165.23	16.13	10.82	47.70	12.75	1.27	0.228
HDL	66.87	59.01	7.86	11.75	17.80	4.76	1.65	0.1226
LDL	96.61	86.36	10.26	10.62	17.44	4.66	2.20	0.0464*
VLDL	31.52	33.23	1.71	5.42	5.33	1.42	1.20	0.2521

1. Effect of trial drug Apamarga Tandula on laboratory parameters:

RESULTS

Effect of trial drug *Apamarga Tandula* on laboratory parameters shows that except FBS and LDL there was statistically insignificant improvement. There was a statistically significant improvement in the FBS (p=0.012) and LDL (p=0.0145). (Table 1)

2. *Effect of trial drug Apamarga Tandula + Vyoshadi Guggulu on laboratory parameters:*

Effect of trial drug *Apamarga Tandula + Vyoshadi Guggulu* on laboratory parameters

shows that except FBS and LDL Cholesterol there was statistically insignificant improvement. There was a statistically significant improvement in the FBS (p=0.0266) and LDL Cholesterol (p=0.0464). (Table 2)

3. *Effect of control drug Sibutramine on laboratory parameters:*

Effect of control drug Sibutramine on laboratory parameters shows that except FBS there was statistically insignificant improvement. There was a statistically significant improvement in the FBS (p=0.089). (Table 3)

Table 3 Effect of Control Drug Sibutramine on Laboratory Parameters [Group C; n=12]

Parameters	Mean		Dif.	% of Change	SD	SE	T	P Value
	BT	AT						
HB	13.70	13.58	0.12	0.85	0.62	0.18	0.65	0.528
TLC	8958.33	10300.00	1341.67	14.98	3126.56	902.56	1.49	0.1652
FBS	100.79	93.74	7.05	6.99	13.08	3.78	1.87	0.089*
Cholesterol	183.36	180.93	2.43	1.32	34.49	9.96	0.24	0.8121
TG	157.79	179.85	22.06	13.98	47.36	13.67	1.61	0.135
HDL	63.18	58.93	4.25	6.72	23.58	6.81	0.62	0.5452
LDL	89.71	83.37	6.34	7.07	20.97	6.05	1.05	0.3173
VLDL	29.28	31.18	1.90	6.49	8.10	2.34	0.81	0.4339

4. *Effect of trial drug Apamarga Tandula on Pratyatma Lakshana parameters:*

Effect of trial drug *Apamarga Tandula* on *Pratyatma Lakshana* parameters shows that there was a statistically significant

improvement in *Gaurava* (p=0.0313), *Kshudha Vriddhi* (p=0.0078), *Swedadhikya* (p=0.0313), *Daurbalya* (p=0.0313), *Ayathopachaya* (p=0.0156), *Udaravriddhi* (p=0.0313), *Alasya* (p=0.0313) and *Anga sada* (p=0.0313). The other *pratyatma lakshanas* such as *Chala Udara* etc. also

showed a consistent improvement but the level of statistical significance was not quite significant. (Table 4) 5. Effect of trial drug *Apamarga Tandula + Vyoshadi Guggulu on Pratyatma Lakshana Parameters:*
Effect of trial drug *Apamarga Tandula + Vyoshadi Guggulu on Pratyatma Lakshana*

parameters shows that there was a statistically significant improvement in *Gaurava* (p=0.0313), *Kshudha Vriddhi* (p=0.0078), *Swedadhikya* (p=0.0313), *Daurbalya* (p=0.0313), *Ayathopachaya*

Table 4 Effect of Trial Drug Apamarga Tandula on Pratyatma Lakshana Parameters [Group A] (Wilcoxon matched-pairs signed-ranks test)

Parameters	N	Mean		Dif.	% of Change	SD	SE	P Value
		BT	AT					
<i>Chala Udara</i>	16	1.69	1.25	0.44	25.93	0.51	0.13	0.0625
<i>Gaurava</i>	16	1.38	0.75	0.63	45.45	0.50	0.13	0.0313*
<i>Kshudha Vriddhi</i>	16	1.38	0.69	0.69	50.00	0.48	0.12	0.0078*
<i>Trishna Vriddhi</i>	8	1.25	0.50	0.75	60.00	0.46	0.16	0.125
<i>Atinidra</i>	11	1.18	0.73	0.45	38.46	0.51	0.15	0.132
<i>Swedadhikya</i>	13	1.23	0.62	0.62	50.00	0.51	0.14	0.0313*
<i>Daurbalya</i>	16	1.56	1.00	0.56	36.00	0.51	0.13	0.0313*
<i>Kricchra Vyavaya</i>	11	1.09	0.82	0.27	25.00	0.47	0.14	0.5
<i>Ayathaopachaya</i>	16	1.50	0.88	0.63	41.67	0.50	0.13	0.0156*
<i>Shaithilya</i>	11	1.09	0.55	0.55	50.00	0.52	0.16	0.0625
<i>Udaravridhi</i>	16	1.69	1.06	0.63	37.04	0.50	0.13	0.0313*
<i>Daurgandhya</i>	13	1.46	0.77	0.69	47.37	0.48	0.13	0.0625
<i>Tandra</i>	10	1.20	0.70	0.50	41.67	0.53	0.17	0.125
<i>Snigdhatrata</i>	16	1.25	0.75	0.50	40.00	0.52	0.13	0.0625
<i>Alasya</i>	16	1.38	0.75	0.63	45.45	0.50	0.13	0.0313*
<i>Angasada</i>	16	1.56	1.00	0.56	36.00	0.51	0.13	0.0313*
<i>Dyspnoea</i>	12	1.25	0.83	0.42	33.33	0.51	0.15	0.125

p=0.0156), *Udaravridhi* (p=0.0313), *Alasya* (p=0.0313) and *Anga sada* (p=0.0313). The other *prayatma lakshanas* such as *Chala Udara* etc. also showed a consistent improvement but the level of

statistical significance was not quite significant. (Table 4)

5. Effect of trial drug *Apamarga Tandula + Vyoshadi Guggulu on Pratyatma Lakshana Parameters:*

Effect of trial drug *Apamarga Tandula* + *Vyoshadi Guggulu* on *Pratyatma Lakshana* parameters shows that there was a statistically significant improvement in *Gaurava* (p=0.0313), *Kshudha Vriddhi* (p=0.0078), *Swedadhikya* (p=0.0313), *Daurbalya* (p=0.0313), *Ayathopachaya*

(p=0.0156), *Udaravridhi* (p=0.0313), *Alasya* (p=0.0313) and *Anga sada* (p=0.0313). The other *prayatma lakshanas* such as *Chala Udara* etc. also showed a consistent improvement but the level of statistical significance was not quite significant.

Table 5 Effect of Trial Drugs *Apamarga Tandula* + *Vyoshadi Guggulu* on *Pratyatma Lakshana* Parameters [Group B] (Wilcoxon matched-pairs signed-ranks test)

Parameters	N	Mean		Dif.	% of Change	SD	SE	P Value
		BT	AT					
<i>Chala Udara</i>	14	1.79	1.29	0.50	28.00	0.52	0.14	0.0625
<i>Gaurava</i>	14	1.21	0.71	0.50	41.18	0.52	0.14	0.0313*
<i>Kshudha Vriddhi</i>	14	1.29	0.64	0.64	50.00	0.50	0.13	0.0078*
<i>Trishna Vriddhi</i>	6	1.17	0.50	0.67	57.14	0.52	0.21	0.125
<i>AtiNidra</i>	11	1.09	0.73	0.36	33.33	0.50	0.15	0.132
<i>Swedadhikya</i>	11	1.18	0.64	0.55	46.15	0.52	0.16	0.0313*
<i>Daurbalya</i>	14	1.57	1.00	0.57	36.36	0.51	0.14	0.0313*
<i>Kricchra Vyavaya</i>	9	1.11	0.89	0.22	20.00	0.44	0.15	0.5
<i>Ayathaopachaya</i>	14	1.36	0.79	0.57	42.11	0.51	0.14	0.0156*
<i>Shaithilya</i>	9	1.11	0.56	0.56	50.00	0.53	0.18	0.0625
<i>Udaravridhi</i>	14	1.57	1.07	0.50	31.82	0.52	0.14	0.0313*
<i>Daurgandhya</i>	11	1.64	1.00	0.64	38.89	0.50	0.15	0.0625
<i>Tandra</i>	7	1.14	0.57	0.57	50.00	0.53	0.20	0.125
<i>Snigdhatratra</i>	14	1.14	0.71	0.43	37.50	0.51	0.14	0.0625
<i>Alasya</i>	14	1.21	0.71	0.50	41.18	0.52	0.14	0.0313*
<i>Angasada</i>	14	1.57	1.00	0.57	36.36	0.51	0.14	0.0313*
<i>Dyspnoea</i>	8	1.25	0.75	0.50	40.00	0.53	0.19	0.125

The statistical significance match almost exactly with that of the group A & C however, the clinical improvement in terms Greentree Group

of percentage varies with the group B showing better results. (Table 5)

6. Effect of control drug *Sibutramine* on *Pratyatma Lakshana* parameters:

Effect of Control Drug *Sibutramine* on *Pratyatma Lakshana* Parameters shows that

there was a statistically significant improvement in *Gaurava* (p=0.0313), *Kshudha Vriddhi* (p=0.0078), *Swedadhikya* (p=0.0313), *Daurbalya* (p=0.0313), *Ayathopachaya* (p=0.0156), *Udaravridhhi* (p=0.0313), *Alasya* (p=0.0313) and *Anga*

sada (p=0.0313). The other *pratyatma lakshanas* such as *Chala Udara* etc. also showed a consistent improvement but the level of statistical significance was not quite significant. (Table 6)

Table 6: Effect of Control Drug Sibutramine on *Pratyatma Lakshana* Parameters [Group C] (Wilcoxon matched-pairs signed-ranks test)

Parameters	N	Mean		Diff.	% of Change	SD	SE	P Value
		BT	AT					
<i>Chala Udara</i>	12	1.67	1.25	0.42	25.00	0.51	0.15	0.0625
<i>Gaurava</i>	12	1.17	0.67	0.50	42.86	0.52	0.15	0.0313*
<i>Kshudha Vriddhi</i>	12	1.25	0.58	0.67	53.33	0.49	0.14	0.0078*
<i>Trishna Vriddhi</i>	5	1.20	0.40	0.80	66.67	0.45	0.20	0.125
<i>AtiNidra</i>	9	1.11	0.67	0.44	40.00	0.53	0.18	0.132
<i>Swedadhikya</i>	10	1.20	0.60	0.60	0.67	0.52	0.16	0.0313*
<i>Daurbalya</i>	12	1.50	1.00	0.50	0.80	0.52	0.15	0.0313*
<i>Kricchra Vyavaya</i>	8	1.13	0.88	0.25	22.22	0.46	0.16	0.5
<i>Ayathaopachaya</i>	12	1.33	0.75	0.58	43.75	0.51	0.15	0.0156*
<i>Shaithilya</i>	8	1.13	0.50	0.63	55.56	0.52	0.18	0.0625
<i>Udaravridhhi</i>	12	1.58	1.08	0.50	31.58	0.52	0.15	0.0313*
<i>Daurgandhya</i>	9	1.56	1.00	0.56	35.71	0.53	0.18	0.0625
<i>Tandra</i>	8	1.13	0.63	0.50	44.44	0.53	0.19	0.125
<i>Snigdhatratra</i>	12	1.17	0.75	0.42	35.71	0.51	0.15	0.0625
<i>Alasya</i>	12	1.17	0.67	0.50	42.86	0.52	0.15	0.0313*
<i>Angasada</i>	12	1.50	1.00	0.50	33.33	0.52	0.15	0.0313*
<i>Dyspnoea</i>	10	1.20	0.80	0.40	33.33	0.52	0.16	0.125

The one-way Analysis of Variance (ANOVA) shows that FBS (p=0.0255) is considered significant. Variation among Group means is significantly greater than expected by chance. While HB (p=0.8823),

7. Effect of the trial and control drugs on laboratory parameters:

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Table 7 Comparison of effect of the Trial Drugs and

Comparison	Mean diff	Q	Remarks	p Value
Group A vs Group B	10.150	3.762	*	P<0.05
Group A vs Group C	1.176	0.4178	Ns	P>0.05
Group B vs Group C	8.974	3.094	Ns	P>0.05

Control Drug on FBS

TLC (p=0.6428), Cholesterol (p=0.8043), TG (p=0.9489), HDL (p=0.8851), LDL (p=0.7064) and VLDL (p=0.8141) considered not significant. (Table 1, 2, 3)

8. Comparison of effect of the trial drugs and control drug on FBS:

Tukey-Kramer Multiple Comparisons Test shows that while q value of Group A vs Group B is 3.762 (p<0.05) which implies that the difference between the two groups is significant, q values of Group A vs Group C (q=0.4178, p>0.05) and Group B vs Group C (q=3.094, p>0.05) show insignificant difference. (Table 7)

9. Effect of the trial and control drugs on Pratyatma Lakshana parameters:

Kruskal-Wallis Test (Nonparametric ANOVA) shows that *Chala Udara* (p=0.9051), *Gaurava* (p=0.7372), *Kshudha Vriddhi* (p=0.9678), *Trishna Vriddhi* (p=0.8831), *Atinidra* (p=0.9329), *Swedadhikya* (p=0.9396), *Daurbalya* (p=0.9266), *Kricchravyavaya* (p=0.9681), *Ayathopachaya* (p=0.9529), *Shaitihilya* (p=0.9377), *Udaravridhi* (p=0.7372),

Daurgandhya (p=0.8119), *Tandra* (p=0.9518), *Snigdhatrata* (p=0.8893), *Alasya* (p=0.7372), *Angasada* (p=0.9266) and *Dyspnoea* (p=0.9063) considered not significant.

DISCUSSION

Laboratory Parameters:

Effect of trial drug *Apamarga Tandula* on laboratory parameters shows that except FBS and LDL Cholesterol there was statistically insignificant improvement. The statistically significant improvement in the FBS (P=0.012) and LDL Cholesterol (P=0.0145). (Table 1)

Effect of Trial Drug *Apamarga Tandula + Vyoshadi Guggulu* on Laboratory Parameters shows that except FBS and LDL there was statistically insignificant improvement. The statistically significant improvement in the FBS (P=0.0266) and LDL (P=0.0464). (Table 2)

Effect of Control Drug *Sibutramine* on Laboratory Parameters shows that except FBS there was statistically insignificant improvement. The statistically significant improvement in the FBS (P=0.089). (Table 3)

One-way Analysis of Variance (ANOVA) for the laboratory parameters among the three groups except FBS shows that the P value is >0.05, considered not significant. This observation implies that the efficacy of

trial drugs is comparable to that of the control drug.

Pratyatma Lakshana parameters:

Effect of Trial Drug *Apamarga Tandula* on *Pratyatma Lakshana* parameters shows that there was a statistically significant improvement in *Gaurava* (p=0.0313), *Kshudha Vriddhi* (p=0.0078), *Swedadhikya* (p=0.0313), *Daurbalya* (p=0.0313), *Ayathopachaya* (p=0.0156), *Udaravridhi* (p=0.0313), *Alasya* (p=0.0313) and *Anga sada* (p=0.0313). The other *Pratyatma lakshanas* such as *Chala Udara* etc. also showed a consistent improvement but the level of statistical significance was not quite significant. (Table 4)

Effect of Trial Drug *Apamarga Tandula* + *Vyoshadi Guggulu* on *Pratyatma Lakshana* Parameters shows that there was a statistically significant improvement in *Gaurava* (p=0.0313), *Kshudha Vriddhi* (p=0.0078), *Swedadhikya* (p=0.0313), *Daurbalya* (p=0.0313), *Ayathopachaya* (p=0.0156), *Udaravridhi* (p=0.0313), *Alasya* (p=0.0313) and *Anga sada* (p=0.0313). The other *Pratyatma lakshanas* such as *Chala Udara* etc. also showed a consistent improvement but the level of statistical significance was not quite significant. The statistical significance match almost exactly with that of the group A & C however the clinical improvement in Greentree Group

terms of percentage varies with the group B showing better results. (Table 5)

Effect of Control Drug *Sibutramine* on *Pratyatma Lakshana* Parameters shows that there was a statistically significant improvement in *Gaurava* (p=0.0313), *Kshudha Vriddhi* (p=0.0078), *Swedadhikya* (p=0.0313), *Daurbalya* (p=0.0313), *Ayathopachaya* (p=0.0156), *Udaravridhi* (p=0.0313), *Alasya* (p=0.0313) and *Anga sada* (p=0.0313). The other *Pratyatma lakshanas* such as *Chala Udara* etc. also showed a consistent improvement but the level of statistical significance was not quite significant. (Table 6)

Kruskal-Wallis Test (Nonparametric ANOVA) on all the *Pratyatma Lakshana* parameters shows that the P value is >0.05, considered not significant. Variation among Group medians is therefore not significantly greater than expected by chance. This implies that the efficacy of trial drugs is comparable to that of the control drug.

At the end of the *Upashayatmaka* study it was seen that there was a significant withdrawal of 15% patients (3/20) from the control *sibutramine* group due to S/S of adverse reactions. The major complaints of these patients were abdominal cramps, constipation and headache.

Probable mode of action of the Trial drug (Achyranthes aspera L.):

The proposed mechanism is that the drug acts on appetite centre and suppresses it. The apparent desensitization of the effects of *A. aspera* could result from either a molecular desensitization (i.e., at the level of the serotonergic or adrenergic receptors proximally activated as a consequence of drug action) or the activation of compensatory pathways to counteract the effects of drug to ensure appropriate caloric supply to the body or maintenance of body weight or it may act by modifying the functioning of the appetite system as measured by subjective changes in feelings of hunger and fullness.

CONCLUSION

Trial groups displayed a comparable result in the laboratory and *Prayatma lakshana* parameters. In variables such as FBS and LDL, the drug *Apamarga Tandula* was found to be better than the control drug. In a

display of synergistic action, trial drugs *Apamarga Tandula* + *Vyoshadi Guggulu* showed the best results in all the parameters, much better than the control drug Sibutramine. When the adverse affects of the control drug Sibutramine are taken into account, it can be safely concluded that the *Apamarga Tandula* is a better drug for the management of obesity especially in combination with *Vyoshadi guggulu* than the control drug Sibutramine. The effects occur because Sibutramine is only an appetite suppressant whereas the combination of *Apamarga Tandula* + *Vyoshadi Guggulu* shows appetite suppressant as well as lipid lowering effects in tandem. For a better assessment of obese individuals, biochemical investigations (like fasting blood glucose, fasting total cholesterol, triglycerides and fasting HDL cholesterol) are necessary to be carried out.

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