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# Role of an Indigenous Compound with Caloric Diet and Fixed Daily Regimen in *Sthaulya* w.s.r to Childhood Obesity

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## ABSTRACT

**INTRODUCTION:** Obesity (*Sthaulya*) is defined as a condition of abnormal or excessive fat accumulation in adipose tissue, to the extent that health may be impaired. (Obesity) is one among the major diseases of modern era. **STUDY TYPE:** Randomised controlled open labelled interventional trial. **AGE GROUP:** Individuals of either sex aged between 5-15 years. **MATERIALS AND METHODS:** Thirty patients of childhood obesity for present study were selected from OPD and IPD of PG Department of *Kaumarbhritya*, NIA, Jaipur after screening them for the same by following different diagnostic criteria's. Various schools in and around Jaipur were also screened for selection of the patients. Selected patients were randomly divided in Group A and Group B, 15 patients in each group. Group A were advised indigenous *Ayurvedic* compound i.e. *Lekhaneeya Gana* Drugs along with *Bilvadi Panchamoola* along with dietary and life style modification and group B were advised to follow strict dietary restrictions which fulfil the caloric requirement of body and instruction Chart was provided for diet and day to day physical and mental exercise. **RESULTS AND CONCLUSION:** Group A administered with trial drug has shown highly significant results in reducing the symptomatology of *Sthaulya* (childhood obesity) and additional effects in normalising the lipid profile in comparison to Group B. However, Group B treated with only caloric diet as per age and dietetic and life style modification has also shown significant results, thus highlighting importance of diet and exercise in effective management of *Sthaulya* (Childhood obesity).

## KEYWORDS

*Bilvadi Panchamoola, Childhood obesity, Indigenous Compound, Lekhaneeya Gana, Sthaulya*

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## INTRODUCTION

As life is becoming more mechanical and living standards of the individual has been greatly money and job oriented, less attention has been given to physical growth and fitness. Attempts were made by parents to enhance the mental faculty of the child so that he can survive in the competitive society while physical fitness has been totally neglected. Less physical exercise, increased academic work load, sedentary life style, intake of junk food leads to increased incidences of obesity. There will be abnormal and excessive accumulation of fat. Unfortunately, the incidences are increasing in children which not only take away the glory of his childhood but also seed many of the future disease.

Adult obesity is difficult to treat and more than 50% of obese children become obese adult with worse complication[1]. Globally, the new international association for the study of obesity / Indian obesity task force (IASO/IOTF) analysis (2010) estimates that up to 200 million schools age children are either overweight or obese, of those 40-50 million are classified as obese[2]. NFHS-3, Rajasthan reported the prevalence of overweight and obesity in male was 8.4 and 10.4 in female[3]. Studies across the country have reported the prevalence of obesity in the range of 3% to 29%. It is found to be more prevalent among urban and educated population with this and its association with the determinants[1,4-8]. The world Health organization in1998 designated obesity as a global epidemic. India is also facing the epidemic of obesity and its associated diseases, especially in children and adolescent. At least 30% of obesity begins in childhood.

Hence the present study has been planned by using the *Ayurvedic* principles in the treatment of *Sthaulya* by administration of indigenous compound indicated for *Sthaulya*. Strict consideration of caloric diet and fixed daily regimen has been implicated in this study. Intake of food as per caloric requirement and fixed daily regimen like exercise, *Yoga*, Meditation and certain daily activities will be strictly followed in the present study.

So in light of above references from classics, indigenous compound which contain *Lekhaneeya Mahakashaya Gana* drugs and *Bilvadi Panchmoola* were selected for the management of *Sthaulya* (Childhood Obesity) in the present research entitled **"Role of an Indigenous Compound with caloric diet and fixed daily regimen in *Sthaulya* w.s.r to Childhood Obesity "** was undertaken with following aims and objectives.

## AIMS AND OBJECTIVES

1. To evaluate the role of an indigenous compound and caloric diet with fixed daily regimen in childhood obesity.

2. To evaluate the role of Dietary and lifestyle modification in case of childhood obesity.

**MATERIALS AND METHODS:**

Ethical Committee Approval Number IEC/ACA/2015/38, 21/05/2015

**SOURCE OF DATA** - Patients of childhood obesity for present study were selected from OPD and IPD of PG Department of Bal roga, NIA, Jaipur after screening them for the same by following different diagnostic criteria's. Various schools in and around Jaipur were also screened for selection of the patients.

**NUMBER OF CASES**: Total 42 cases were registered out of which 12 children discontinued the treatment during the course in present clinical study for various reasons.

**STUDY TYPE:** Randomised controlled open labelled interventional trial.

**GROUPING OF PATIENTS:**

Selected patients were randomly divided in Group A and Group B.

**GROUP A** – In this group 15 patients were advised indigenous *Ayurvedic* compound along with dietary and life style modification.

**GROUP B** – In this group 15 patients were advised to follow strict dietary restrictions which fulfil the caloric requirement of body and instruction Chart will be provided for diet and day to day physical and mental exercise.

**METHOD OF DRUG PREPARATION :-** *Lekhaneeya* and *Medohara* drugs mentioned in classics were taken in powder form in equal quantity and given *Bhavana* with *Bilvadi- panchamoola Gana* drugs and *Vati* were prepared and given twice daily with *Madhhudaka*.

Diet and regimen chart were prepared as per age and weight of the child after referring various literatures and previous studies.

**DOSE**- *Vati* of 5gram was prepared in the present study. Dose of the trail drug in the present study was 10grams /day and administered in two equally divided doses with *Madhudaka* as *Anupana*. Trail drug was triturated with *Kashaya* prepared by *Bilvadi panchamoola* drugs.

**DURATION** – Total duration of the intervention was six month.

**INCLUSION CRITERIA:-**

1. Individuals of either sexes aged between 5-15 years.
2. Children with familial tendency of obesity.
3. Obesity due to abnormal lifestyle and dietary habits.
4. Individuals having BMI more than 85$^{th}$ percentile of CDC growth charts 2000.

**EXCLUSION CRITERIA:-**

1. Children who will be suffering from any systemic and endocrinal illness like DM, Hypothyroidism etc.

2. Obesity associated with chromosomal disorders.

3. Children who are already on treatment for obesity or other disorders.

4. Drug induced obesity.

**DISCONTINUATION CRITERIA:-**

1. Appearance of any adverse effect of drug during trial.

2. Parent or child not willing to continue with the medicine.

3. Any other acute illness.

**ASSESSMENT CRITERIA:-**

Assessment of effects of the therapy was done on the basis of various subjective and objective criteria. For the purpose of assessment a detailed clinical research Performa was prepared incorporating various parameters like *Dashavidha Pariksha, Ashtavidha Pariksha* etc. Patients were thoroughly assessed during the trial period after every fifteen days. Following objective and subjective parameters were adopted for assessment.

**1. OBJECTIVE CRITERIA-**

(a) BMI- Body Mass Index of the child was assessed before and after the treatment by the formula as

BMI = Weight (kg)/Height $(m)^2$

CDC growth charts (2000) were used to know age-sex specific BMI.

(b) Body Fat Analysis: Total body fat percentage was calculated using body fat analyser.

(c) Anthropometry-

1. Body weight

2. Body height

(d) Laboratory Investigation-

1. Total serum cholesterol

2. Triglycerides

3. HDL, LDL, VLDL

**2. SUBJECTIVE CRITERIA-**

To assess the improvement in clinical symptomatology of the patients, scoring system was adopted. Symptoms were accorded grades according to their severity.

**Instructions to the Patients:**

All registered patients were given following advice:

✓ Not to discontinue the trial drug until the trial was over.

✓ Not to take any medication during the trial period.

✓ To continue with their normal food habits but not to overeat or indulge in high calorie and high fat diet.

✓ To attend the hospital for regular follow-up as per protocol.

✓ To play outdoor games / cycling / skipping / for 30-60 minutes daily.

✓ Food charts were given to the parents as follows: [Provided by Dr. Nimali Singh. Associate Professor, Department of Home

Science, Rajasthan University, Jaipur (Rajasthan)]

✓ Sample menu of diet were provided to the parents as per age of the children, which is as follows: [Provided by Dr. Nimali Singh. Associate Professor, Department of Home Science, Rajasthan University, Jaipur (Rajasthan)]

**Follow-up Schedule:**

All patients were called for follow-up after every 15 days. During follow-ups patients were thoroughly evaluated on various subjective and objective criteria. Untoward effects were also observed and recoded in case research Performa.

## RESULTS AND DISCUSSION

A total of 30 patients were registered from the O.P.D. and I.P.D., Department of *Kaumarbhritya*, National Institute of Ayurveda (NIA) Jaipur, Rajasthan. They were randomly divided into Trial Group-A (n=15), Trial Group-B (n=15). Under this study, 08 sign and symptoms were assessed before and after treatment.

### A. CLINICAL IMPROVEMENT PROFILE.

**Table 1** Statistical analysis of *Chala Sphika Udara Stana*

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 1.93 | 1.13 | 0.80 | 41.45 | 0.560 | 0.144 | 10.583 | 0.0010 | E.S |
| B | 15 | 1.20 | 0.73 | 0.46 | 38.33 | 0.639 | 0.165 | 16 | 0.01 | S |

The initial mean score in the symptom was recorded as 1.93 in Group A and 1.20 in Group B, which was reduced to 1.13 in Group A and 0.73 in Group B, after the therapy. The percentage of relief observed was 41.45% (Mild Relief) in Group A and 38.33% (Mild Relief) in Group B. The result in group A was statistically extremely significant ($p<0.0010$) and in group B was statistically significant ($p<0.01$), but percentage relief was maximum in group A. (Table 01 & Fig. No. 01)

**Table 02** Statistical analysis of *Alasya / Utsahahan*

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 1.26 | 0.46 | 0.80 | 63.49 | 0.774 | 0.200 | 8.264 | 0.001 | V.S |
| B | 15 | 1.26 | 0.73 | 0.53 | 42.06 | 0.639 | 0.165 | 4.58 | 0.01 | S |

The initial mean score in the symptom was recorded as 1.26 in both Group A and Group B, which was reduced to 0.46 in Group A and 0.73 in Group B after the therapy. The percentage of relief observed was 63.49% (Moderate Relief) in Group A and 42.06% (Mild Relief) in Group B. The result in group A was statistically very

significant (p<0.001) and in group B was statistically significant (p<0.01), but percentage relief was maximum in group A. (Table 02 & Fig. No. 01).

**Table 03** Statistical analysis of *Kshudra Swasa*

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 0.93 | 0.40 | 0.53 | 56.98 | 0.516 | 0.133 | 5.905 | 0.001 | V.S |
| B | 15 | 0.86 | 0.46 | 0.40 | 46.51 | 0.507 | 0.130 | 5.29 | 0.01 | S |

The initial mean score in the symptom was recorded as 0.93 in Group A and 0.86 in Group B, which was reduced to 0.40 in Group A and 0.46 in Group B, after the therapy. The percentage of relief observed was 56.98% (Moderate Relief) in Group A and 46.51% (Mild Relief) in Group B. The result in group A was statistically very significant (p<0.001) and in group B was statistically significant (p<0.01), but percentage relief was maximum in group A. (Table 04 & Fig. No. 01)

**Table 04** Statistical analysis of *Nidradhikya*

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | REM |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 1.40 | 0.46 | 0.93 | 66.42 | 0.883 | 0.228 | 7.245 | 0.001 | V.S |
| B | 15 | 0.80 | 0.60 | 0.20 | 25.00 | 0.414 | 0.106 | 9.025 | 0.1 | N.S |

The initial mean score in the symptom was recorded as 1.40 in Group A and 0.80 in Group B, which was reduced to 0.46 in Group A and 0.60 in Group B, after the therapy. The percentage of relief observed was 66.42% (Moderate Relief) in Group A and 25.00% (Mild Relief) in Group B. The result in group A was statistically very significant (p<0.001) and in group B was statistically not significant (p<0.1), but percentage relief was maximum in group A. (Table 05 & Fig. No. 01)

**Table 05 S**tatistical analysis of *Swedadhikya*

| Groups | N | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 0.73 | 0.40 | 0.33 | 45.20 | 0.617 | 0.159 | 6.324 | 0.1 | N.S |
| B | 15 | 0.60 | 0.46 | 0.13 | 21.66 | 0.351 | 0.090 | 6.859 | 0.1 | N.S |

The initial mean score in the symptom was recorded as 0.73 in Group A and 0.60 in Group B, which was reduced to 0.40 in Group A and 0.46 in Group B, after the therapy. The percentage of relief observed was 45.20% (Mild Relief) in Group A and 21.66% (Mild Relief) in Group B. The result in both groups was statistically not significant (p<0.1), but percentage relief

was maximum in group A. (Table 06 & Fig. No. 01)

The initial mean score in the symptom was recorded as 0.53 in Group A and 0.53 in Group B also

**Table 06** Statistical analysis of *Daurgandhya*

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 0.53 | 0.26 | 0.26 | 49.05 | 0.457 | 0.118 | 6.5 | 0.1 | N.S |
| B | 15 | 0.53 | 0.33 | 0.20 | 37.73 | 0.414 | 0.106 | 9.53 | 0.1 | N.S |

, which was reduced to 0.26 in Group A and 0.33 in Group B, after the therapy. The percentage of relief observed was 49.05% (Mild Relief) in Group A and 37.73% (Mild Relief) in Group B. The result in both groups was statistically not significant ($p<0.1$), but percentage relief was maximum in group A.

**Table 07** Statistical analysis of *Ati Pipasa:*

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 0.66 | 0.13 | 0.53 | 80.30 | 0.516 | 0.133 | 6.971 | 0.001 | V.S |
| B | 15 | 0.40 | 0.26 | 0.13 | 32.50 | 0.351 | 0.090 | 8.366 | 0.1 | N.S |

The initial mean score in the symptom was recorded as 0.66 in Group A and 0.40 in Group B, which was reduced to 0.13 in Group A and 0.26 in Group B, after the therapy. The percentage of relief observed was 80.30% (Marked Relief) in Group A and 32.50% (Mild Relief) in Group B. The result in group A was statistically very significant ($p<0.001$) and in group B was statistically not significant ($p<0.1$), but percentage relief was maximum in group A.

**Table 08** Statistical analysis of *Ati Kshudha*

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 1.06 | 0.13 | 0.93 | 87.73 | 0.798 | 0.206 | 6.5 | 0.001 | V.S |
| B | 15 | 0.86 | 0.33 | 0.53 | 61.62 | 0.639 | 0.165 | 8.366 | 0.01 | S |

The initial mean score in the symptom was recorded as 1.06 in Group A and 0.86 in Group B, which was reduced to 0.13 in Group A and 0.33 in Group B, after the therapy. The percentage of relief observed was 87.73% (Marked Relief) in Group A and 61.62% (Moderate Relief) in Group B. The result in group A was statistically very significant ($p<0.001$) and in group B was statistically significant ($p<0.01$), but percentage relief was maximum in group A.

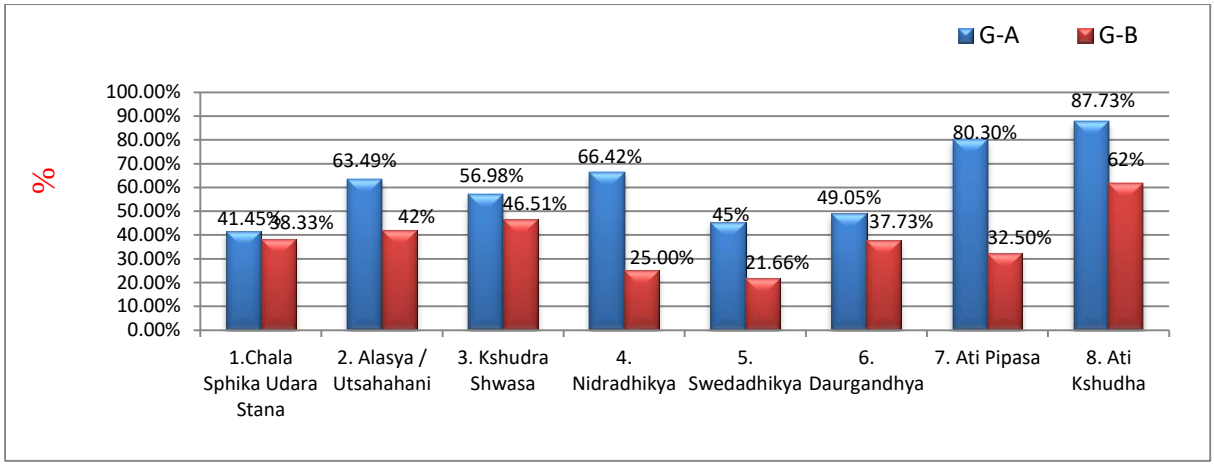


**Fig. 1** Percentage improvement in subjective parameter

## ANTHROPOMETRIC IMPROVEMENT PROFILE

**Table 09 Analysis of Body Weight:**

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 47.80 | 44.66 | 3.13 | 6.54 | 1.302 | 0.336 | 9.320 | 0.0001 | E.S |
| B | 15 | 49.86 | 47.60 | 2.26 | 4.53 | 0.703 | 0.181 | 12.475 | 0.0001 | E.S |

The body weight measured in all cases before trial had a mean of 47.80 in Group A, 49.86 in Group B, and after treatment it was reduced to 44.66 in Group A, 47.60 in Group B. The percentage of improvement was 6.54% in Group A and 4.53% in Group B. Statistically, both are extremely significant ($p<0.0001$). (Table 09 & Fig. No. 02)

**s**BMI calculated in all cases before trial had a mean of 24.13 in Group A, 24.40 in Group B, and after treatment it was reduced to 22.00 in Group A, 22.93 in Group B. The percentage of improvement was 8.82% in Group A and 5.98% in Group B. statistically, both are extremely significant ($p<0.0001$). (Table 10 & Fig. No. 02)

**Table 11** Statistical analysis of Body Fat Percentage:

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 27.86 | 24.72 | 2.85 | 10.22 | 1.069 | 0.276 | 10.361 | 0.0001 | E.S |
| B | 15 | 27.71 | 25.45 | 2.56 | 9.23 | 1.136 | 0.293 | 7.689 | 0.0001 | E.S |

Body fat percentage calculated in all cases before trial had a mean of 27.86 in Group A, 27.71 in Group B, and after treatment it was reduced to 24.72 in Group A, 25.45 in Group B. The percentage of improvement was 10.22% in Group A and 9.23% in Group B. statistically, both are extremely significant ($p<0.0001$). (Table 11 & Fig. No. 02)

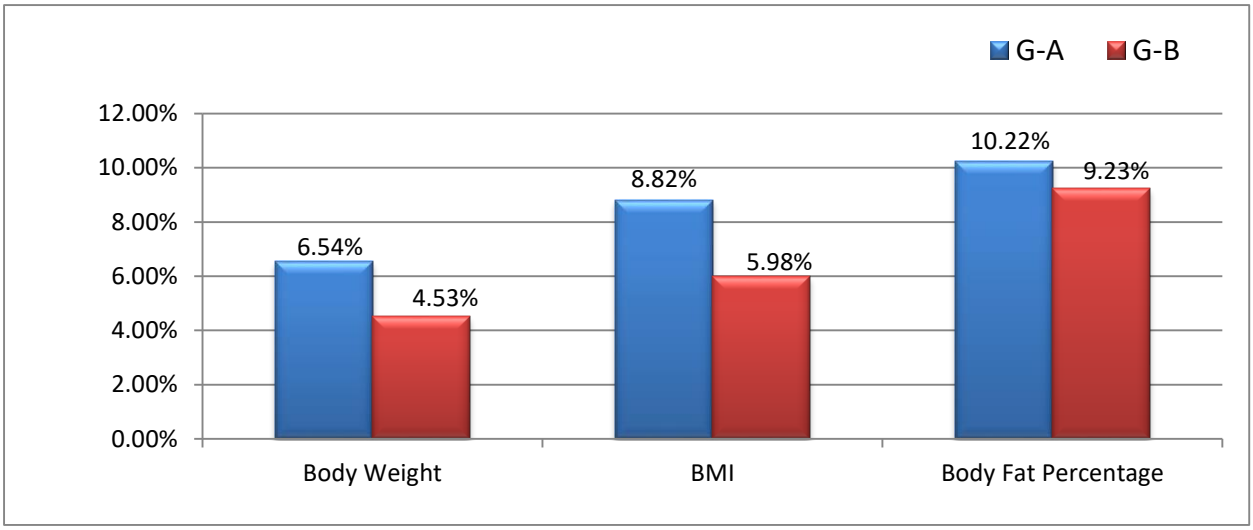


**Fig.2** Percentage improvement in Anthropometric Profile

## BIOCHEMICAL IMPROVEMENT PROFILE

**Table 12** Statistical analysis of Serum Cholesterol

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| **A** | 15 | 168.28 | 150.87 | 17.41 | 10.34 | 7.444 | 1.922 | 9.059 | 0.0001 | E.S |
| **B** | 15 | 165.27 | 157.87 | 7.40 | 4.47 | 7.385 | 1.907 | 3.881 | 0.0017 | VS |

It was found to have a mean of 168.28 in Group A, 165.27 in Group B, and after treatment it was reduced to 150.87 in Group A, 157.87 in Group B. The percentage of improvement was 10.34% in Group A and 4.47% in Group B. The result in group A was statistically extremely significant ($p<0.0010$) and in group B was statistically very significant ($p<0.001$). (**Table 12 & Fig no. 03)**

It was found to have a mean of 123.62 in Group A, 123.20 in Group B, and after treatment it was reduced to 111.67 in Group A, 117.13 in Group B. The percentage of improvement was 9.66% in Group A and 4.92% in Group B. The result in group A was statistically extremely significant ($p<0.0010$) and in group B was statistically very significant ($p<0.001$). (**Table 13 & Fig no. 03)**

**Table 13** Statistical analysis of Serum Triglycerides:

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| **A** | 15 | 123.62 | 111.67 | 11.95 | 9.66 | 4.975 | 1.284 | 9.306 | 0.0001 | E.S |
| **B** | 15 | 123.20 | 117.13 | 6.067 | 4.92 | 5.688 | 1.469 | 4.131 | 0.0010 | V.S |

**Table 14** Statistical analysis of High Density Lipoproteins (HDL)

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 46.72 | 51.60 | -4.88 | 10.44 | 2.265 | 0.584 | 8.344 | 0.0001 | E.S |
| B | 15 | 45.16 | 47.00 | -1.84 | 4.07 | 1.667 | 0.430 | 4.275 | 0.0008 | E.S |

**Table 15** Statistical analysis of Low Density Lipoproteins (LDL)

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 92.12 | 84.00 | 8.12 | 8.81 | 4.618 | 1.192 | 6.816 | 0.0001 | E.S |
| B | 15 | 97.72 | 94.86 | 2.86 | 2.92 | 4.051 | 1.046 | 2.740 | 0.0159 | S |

It was found to have a mean of 46.72 in Group A, 45.16 in Group B, and after treatment it was increased to 51.60 in Group A, 47.00 in Group B. The increased percentage was 10.44% in Group A, Which are statistically extremely significant ($p<0.0001$), and 4.07% in Group B, which are also statistically extremely significant ($p<0.0008$). (**Table 14 & Fig no. 03)**

It was found to have a mean of 92.12 in Group A, 97.72 in Group B, and after treatment it was reduced to 84.00 in Group A, 94.86 in Group B. The percentage of improvement was 8.81% in Group A, which are statistically extremely significant ($p<0.0001$), and 2.92% in Group B, which are statistically significant ($p<0.0159$). (**Table 15 & Fig no. 03)**

**Table 16** Statistical analysis of Very Low Density Lipoproteins (VLDL)

| Groups | "n" | Mean | | | Relief % | S.D. | S.E. | "t" | "p" | Result |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | X | | | | | | |
| A | 15 | 26.56 | 20.18 | 6.38 | 24.02 | 5.896 | 1.522 | 4.191 | 0.0009 | E.S |
| B | 15 | 23.30 | 22.83 | 0.46 | 1.97 | 2.932 | 0.757 | 0.616 | 0.5475 | N.S |

It was found to have a mean of 26.56 in Group A, 23.30 in Group B, and after treatment it was reduced to 20.18 in Group A, 22.83 in Group B. The percentage of improvement was 24.02% in Group A, which are statistically extremely significant ($p<0.0009$), and 1.97% in Group B, which are statistically not significant ($p<0.5475$). (**Table 16 & Fig no. 03)**

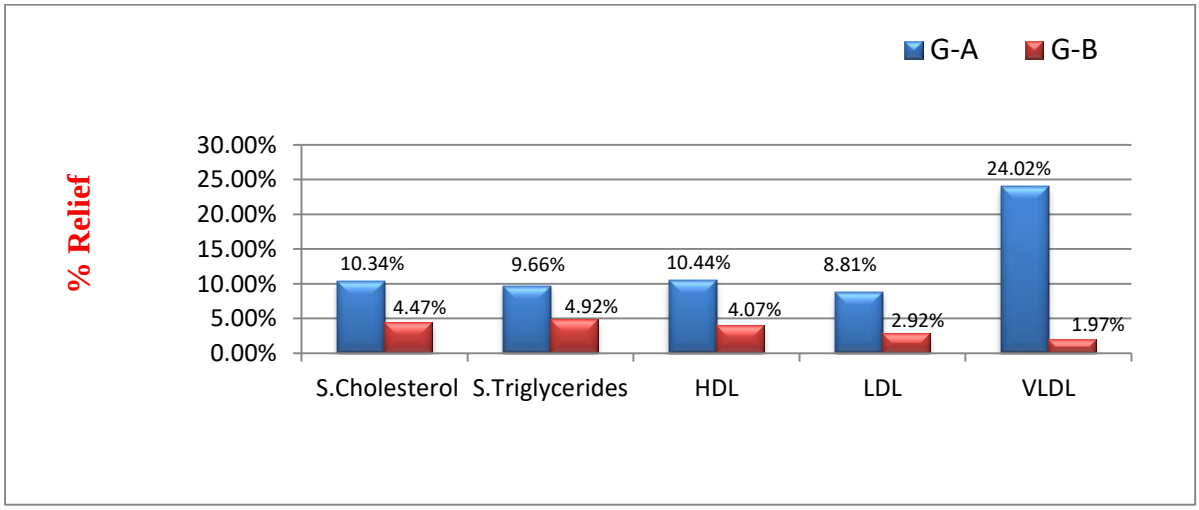


**Fig. 3** Percentage improvement in Biochemical Profile

**Table 17** Statistical analysis of inter group comparison after treatment of *Lakshanas* (Symptoms)

| S.N | *Lakshana*(Symptoms) | Group (A.T.) | Mean ± SD | SE | Mann-Whitney U | P value | Rem. |
|---|---|---|---|---|---|---|---|
| **1** | *Chala Sphika Udara Stana* | A | 0.80±0.560 | 0.144 | 77.50 | 0.1084 | NS |
| | | B | 0.466±0.639 | 0.165 | | | |
| **2** | *Alasya* | A | 0.800±0.774 | 0.200 | 91.50 | 0.3515 | **NS** |
| | | B | 0.533±0.639 | 0.165 | | | |
| **3** | *Nidradhikya* | A | 0.933±0.883 | 0.228 | 60.00 | 0.0139 | **S** |
| | | B | 0.200±0.414 | 0.106 | | | |
| **4** | *Swedahikya* | A | 0.333±0.617 | 0.159 | 96.50 | 0.3554 | **NS** |
| | | B | 0.133±0.351 | 0.090 | | | |
| **5** | *Daurgandhya* | A | 0.266±0.457 | 0.118 | 105.00 | 0.6920 | **NS** |
| | | B | 0.200±.414 | 0.106 | | | |
| **6** | *Atipipasa* | A | 0.533±0.516 | 0.133 | 67.500 | 0.0239 | **S** |
| | | B | 0.133±0.351 | 0.090 | | | |
| **7** | *Atikshudha* | A | 0.9333±0.798 | 0.206 | 81.00 | 0.1634 | NS |
| | | B | 0.533±0.639 | 0.165 | | | |
| **8** | *Kshudra Shwasa* | A | 0.533±0.516 | 0.133 | 97.50 | 0.4867 | NS |
| | | B | 0.400±0.507 | 0.130 | | | |

From above table it can be seen that there is a statistically significant difference (P<0.05) found in the effect of therapies in both groups on *Nidradhikya* and *Attipipasa* and no significant difference (P>0.05) found on rest of *Lakshanas* (symptoms). (**Table 17**)

**Table 18** Statistical analysis of inter group comparison after treatment of Lab investigation.

| **S.N** | **Investigation** | **Group (A.T.)** | **Mean ± SD** | **SE** | **t value** | **P value** | **Rem.** |
|---|---|---|---|---|---|---|---|
| 1 | S. Cholesterol | A | 17.41± 7.444 | 1.922 | 3.698 | 0.0009 | **E.S** |
| | | B | 7.40± 7.385 | 1.907 | | | |
| 2 | Triglyceride | A | 11.95± 4.975 | 1.284 | 3.017 | 0.0054 | **V.S** |
| | | B | 6.06± 5.688 | 1.469 | | | |
| 3 | HDL | A | -4.88± 2.265 | 0.584 | 4.187 | 0.0003 | **E.S** |
| | | B | -1.84± 1.667 | 0.430 | | | |
| 4 | LDL | A | 8.127± 4.618 | 0.584 | 3.316 | 0.0025 | **V.S** |
| | | B | 2.86 4.051 | 0.430 | | | |
| 5 | VLDL | A | 6.44± **6.095** | 1.192 | 3.424 | 0.0019 | **V.S** |
| | | B | 0.46± 2.932 | 0.757 | | | |

From above table it can be seen that there is a statistically extremely significant difference (P<0.05) found in the effect of therapies in both groups on S.Cholesterol and HDL level and very significant difference (P>0.05) found on Triglyceride, LDL and VLDL level. (**Table 18**)

**Table 19** Statistical analysis of inter group comparison after treatment of Parameters.

| **S.N** | **Parameters** | **Group (A.T.)** | **Mean ± SD** | **SE** | **t value** | **P value** | **Rem.** |
|---|---|---|---|---|---|---|---|
| 1 | **Weight(kg)** | A | 3.13±1.302 | 0.336 | 2.268 | 0.0312 | **S** |
| | | B | 2.26±0.703 | 0.181 | | | |
| 2 | **BMI** | A | 2.13±0.743 | 0.191 | 2.457 | 0.0205 | **S** |
| | | B | 1.46±0.743 | 0.191 | | | |
| 3 | **Body Fat Percentage** | A | 2.85±1.069 | 0.276 | 1.498 | 0.1454 | **N.S** |

From above table it can be seen that there is a statistically significant difference (P<0.05) found in the effect of therapies in both groups on Weight and BMI and no significant difference (P>0.05) found on body fat percentage. Result shows that the efficacy of Group A is more than Group B for reducing body weight and BMI.

## DISCUSSION

**Regarding Probable mode of action of Group A (Indigenous Compound along with Dietary and life style modification):** *Sthaulya* which is a *Rasa Nimittaja Vyadhi* as well as *Sleshmaja Nanatamaja Vyadhi* and has been also considered under the *Santarpanotha* disorders or disease due to improper and over nourishment. Present study has been planned to break the pathogenesis of the *Sthaulya* by administration of *Lekhaneeya Gana* drugs processed with *Bilvadi Panchmula Gana* drugs along with strict dietary instruction with caloric diet.

1. ***Nidana parivarjana***[9] - Certain dietic factors like *Ati Snigdha, Ati Madhura Ahara, Ati Santarpana* and other *Kapha* increasing diet which acts as high caloric food, life style related factors, reduced exercise, sedentary life are the major causative factors. In the present study counselling of the child as well as parents were done prior to administration of the drug in this regard to avoid all possible causative factors, and list of food beverages to be taken with interval and daily activities to be done has been provided.

2. **Dietic instructions**- Intake of *Ati Singdha, Ati Madhura* and *Medo Vardaka Ahara* leads to accumulation of the fat in the body. Intake of complete and balanced food is key factor with consideration *Ahara parinamakara Bhava and Astha vidha Ahara vidhi visheshayatan* has been explained to the patients. Hence strict dietary instructions were given the study regarding do and don'ts with regards to food. Heavy food materials with less caloric value have been advised like fibres rich diet (*Guru cha Apatarpana*) and predominantly *Vatahara Annapana* has been indicated[10].

3. ***Vihara* instruction**- Intake of high caloric food with reduced exercise and more sedentary habits leads to accumulation of the fatty materials in the body which later gets deposited in different parts of the body. So in the present study a proper schedule has been provided to the patients so that they have enough exercise. Child and parents were encouraged to involve in different activities with physical exercise like dancing, skipping, cycling, swimming etc[11].

4. **Life style modification** – In the present study it has been found that

maximum families follow a mechanical life style with busy schedule. Day completes with routine works like school, home work, T.V watching, readymade fast food etc with improper eating habits. Attempt has been made in the present study to correct the same[12].

5. **Psychological counselling** – Self awareness about the severity of the disease in future regarding its complication is quite important in effective management of obesity. Children are not aware of such factors may be reluctant to withdraw certain junk food, sweetish items, and like more sedentary life. In the present study attempt has been made to identify such children and counselling was done.

6. ***Sleshmahara Chikitsa[13]***- Increase in the *Kapha* due to intake of causative factors is the major factor to be corrected in this disease. Although *Kapha* is vital to sustain the body, *Mala Rupi Kapha* when get deposited in the body become more hazardous to the body. In the present study attempt has been made to keep the *Sleshma* under the physiologic limit to avoid its hazards by trail drug. Most of the drugs in the Indigenous Compound are having *Laghu, Ruksha, Tikshna, Ushna Veerya and Tikta rasa* property which are antagonistic to *Kapha which* helps in *Kaphashamana.*

*7.* ***Medhohara Chikitsa***- *Medo Dhatu* is the main culprit in the pathology of *Sthaulya*. Improper food habits with more *Prithwi* and *Jala Mahabhuta* dominant diets in the presence of underlying *Agnimandhya*[14] leads to abnormal formation as well accumulation of the *Meda* in the body which later on collected at different parts of the body and also obstructs the path of *Vata* in *Kostha*. Drugs present in the *Lekhaneeya Gana* found more useful in elevating the abnormal *Meda* in the body due its anti – lipidemic properties.

8. ***Agni Vardana Chikitsa and Medho Dhatawaganimandhya Chikitsa*** – *Ayurveda* is based on basic principle that all the disorders are due to *Mandagni*. Hence properties of *Lekhaneeya Mahakashaya*, increase the *Agneya bhava* in the body and acts as '*Jatharaagni'* promoting formulation. *Jatharaagni* stimulation corrects hypo functioning of *Medo Dhatwagni* and checks increase in the quantity and subsequent deposition of *Medo Dhatu* in the body. *Laghu guna* of the drugs increase '*Vayu* and *Agni Mahabhuta*.' While *Tikshna Guna* is constituted by *Agni Mahabhuta*. These drugs perform action of *Shodhana, Lekhana* and *Kaphahara karma*. Further dugs of *Bilvadi Panchmula* possess *Kashaya* and *Tikta Rasa. Kashaya* which are also useful to check the further

deposition of *Meda* and to increase the *Agneya Bhava.*

**Discussion regarding Group B (Dietary and life style modification)-** However, Group B which was advised only with life style modification and caloric food (by providing diet chart as per age) has also shown significant results as role of diet, exercise, caloric food in the management of obesity is obvious and proved by previous research works.

## CONCLUSION

The present study entitled **Role of an Indigenous Compound with caloric diet and fixed daily regimen in *Sthaulya* w.s.r to Childhood Obesity** in 30 patients of childhood obesity was planned as randomised controlled open labelled interventional trial, and following conclusions were drawn.

1. The study showed that 11-15 years of age as more prone period for developing childhood obesity with increased incidences in male children.
2. Present study has also shown definite role of socio-economical status, sedentary and mechanical life style with inclination towards junk food as common precipitating factor for development of *Sthaulya* (childhood obesity).
3. Group A administered with trial drug i.e. *Lekhaneeya Gana* Drugs along with *Bilvadi Panchamoola* has shown highly significant results in reducing the symptomatology of *Sthaulya* (childhood obesity) in comparison to Group B.
4. However, Group B treated with only caloric diet as per age and dietetic and life style modification has also shown significant results, thus highlighting importance of diet, exercise in effective management of *Sthaulya* (Childhood obesity)
5. Further, Group A has shown additional effects in normalising the lipid profile as well as highly significant results in all subjective and objective criteria's for assessment of the present study, proving trail drug as an effective anti obesity and hypolipidimic drug.
6. Hence, it is concluded that combination of caloric diet, life style management and an anti obesity and hypo lipidimic drug in the form of *Lekhaneeya Gana* Drugs and *Bilvadi Panchamoola* can be used as ideal treatment in management of *Sthaulya* in children.
7. Further, study may be conducted on the same drug with large sample size for longer duration to explore the effective therapeutic use.

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