Clinical Research

A clinical study on the role of Agnimanthadi compound in the management of Sthaulya (obesity)

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Abstract

Sthaulya (obesity) has become so common in the World’s population that it is beginning to replace undernutrition and infectious diseases as the most significant contributor to ill health. It exacerbates a large number of health-related problems, both independently and in association with other diseases. Therefore, this study was carried out at PG Hospital, IPGT and RA, Jamnagar to evaluate effect of Agnimanthadi compound in the patients of Sthaulya. For this purpose 83 patients of Sthaulya were selected out of which 15 patients were dropped out. Remaining 68 patients were treated in two groups. Among these, 38 patients of Sthaulya were treated with Agnimanthadi compound administered orally in the dose of four capsules of 500 mg three times a day with lukewarm water before meal. Remaining 30 patients of Sthaulya were kept as placebo control and were administered orally two placebo capsules of 500 mg filled with starch, three times a day with lukewarm water before meal. The duration of the treatment in both the groups was 7 weeks with follow-up for 2 months. Analysis of overall effects of both the groups showed that Agnimanthadi compound provided markedly better reduction in weight, BMI and other signs and symptoms in the patients of obesity in comparison to the control group.

Key words: Agnimanthadi compound, obesity, sthaulya

Introduction

Sthaulya is included under eight undesirable conditions (Ashtau Nindita),[1] Shleshma Nanatmaja,[2] Samtarpana Nimitsulta,[3] Atmitinda,[4] Ati Brihmana Nimitsulta[5] and Bahu Dosha Janita[6] Vikara. Moreover Sushruta has emphasized on metabolic disturbances (Dhatvaagnimandya) in the etiopathogenesis of Sthaulya.[7] The patient of Sthaulya exhibits very strange phenomenon. Their appetite is excessive[8] and whatever they eat is quickly digested, which indicates hyperfunctioning of the Jatharaagni. Besides this, the patient suffers from laziness, may be due to under supply of energy, which may be due to hypofunctioning of Bhutaagni. Further Dhatvaagni also seems to be disturbed, as in Sthaulya patient mainly Medo-Dhatu is formed and there is deficiency of other Dhatu.[9] Hence, it can be inferred that in Sthaulya, Jatharaagni is Tikshna, Bhutaagni is Manda and Dhatvaagni is disturbed in their respective functions. On the basis of the above-mentioned facts of pathogenesis of Sthaulya, it can be said that the drug, which decreases Jatharaagni particularly Abhyaharana Shakti, increases Bhutaagni and corrects the functions of Dhatvaagni and at the same time have Medo-hara, Kapha-hara and Vatahara actions, may be suitable for its management.

Taking all the above mentioned facts in consideration, Agnimanthadi compound comprising of Agnimanththa, Mustaka, Gomutra and Eranda Patra Kshara was formulated for the present study. Most of these drugs are indicated in the treatment of Sthaulya in Ayurvedic classics.[10]

Agnimantha (Clerodendrum phlomidis (Burm.f.) Kuntze) is Dipana, Pachana, Kaphaghna, Shothahara and is having Vata-Kapha Hara properties.[11] Its antidiabetic action[12] is also reported which may be due to its action at the level of Bhutaagni and Dhatvaagni. Mustaka (Cyperus rotundus Linn) has Dipana, Pachana, Lekhana, Mutrala and Pitta Shamaka actions.[13] To make both drugs more Tikshna, seven Bhavana of Gomutra were given. Gomutra is Tikshna, Ushna and Agni-Dipaka in action[14] and has Kapha Vata Nashaka properties. It is also indicated in the treatment of Sthaulya by Sushruta.[7]

In clinical practice it is observed that Agnimantha produces burning sensation. Hence, Eranda (Ricinus communis Linn) Patra Kshara was added in the compound, which is reported to have Kapha Nashaka, Medohara, Dipana and Pachana actions.[15]
Objective
1. To evaluate the efficacy of Agnimanthadi compound in the management of Sthaulya (obesity)

Materials and Methods

The 83 patients of Sthaulya (obesity) attending the OPD and IPD of PG Hospital, IPGT and RA, Gujarat Ayurveda University, Jamnagar were registered for this study. Out of these, 15 patients were dropped out and 68 patients completed the prescribed course of the treatment.

Criteria of diagnosis
The diagnosis was mainly based on the clinical presentation as mentioned in the Ayurveda texts as well as Allopathic texts along with body mass index (BMI). A detailed proforma incorporating all the clinical aspects mentioned for Sthaulya/obesity was prepared accordingly, detailed clinical history was taken and physical examination was done.

Criteria for selection of patients
Patients in the age group of 16-65 years were selected for the present study. Other criteria for inclusion was as follow:

Subjective criteria
- Patients having clinical presentation of Sthaulya (obesity) as mentioned in the Ayurveda texts as well as allopathic texts.

Objective criteria
- For the present study BMI more than 30 was taken for considering the patients as obese and the patients having BMI 30-45 were included for the present study.

Exclusion criteria
- Patients in the age group of less than 16 years and more than 65 years were not included for the present study.
- Obese patients suffering from hypothyroidism, obesity due to hormonal imbalance, cardiovascular diseases, hemiplegia, associated with severe hypertension and from other such diseases in which the patient cannot do his routine physical activities were excluded.
- Very obese patients having BMI more than 45 were excluded from the present study.

Investigations
- Lipid profile was carried out approximately in all the patients before and after the study and fasting blood sugar was carried out in suspected cases only.

Other examination and tests
- Weight was recorded before starting the treatment and later on every week of the study. Weight was also recorded of all the patients who have come for the follow-up study.
- Circumferences of fatty parts were recorded before and thereafter every week, till the completion of the course of treatment, to assess the effect of therapy.
- The effectiveness of therapy on body fat was assessed by measuring the skin fold thickness by vernier calipers before and after the treatment in particular areas of middle portions of the biceps and triceps muscles, middle portion of the suprailiac region and the anterior surface of mid-thigh region and of abdominal muscle at umbilicus.
- Walking time: The time taken to climb fixed number of stairs in seconds was taken as walking time.

Groups division and treatment
Eighty-three patients of Sthaulya were registered for this study and were divided into two groups viz. Placebo control group and Agnimanthadi group. Out of which 15 patients were dropped out and 68 patients of Sthaulya completed the full-course of the treatment and their details were as follow:

(1) Control (C) Group: The patients of this group were given two placebo capsules three times a day with lukewarm water before meal for seven weeks. Each capsule was filled with 500 mg of starch.

(2) Agnimanthadi (A) Group: Patients of this group were administered Agnimanthadi compound in the dose of 2 g (four capsules of 500 mg) three times a day with lukewarm water before meal for a period of 7 weeks.

Method of preparation of drug
Agnimantha compound comprises of four drugs namely Agnimanta, Mustaka, Eranda Patra Kshara and Gomutra. First of all, fine powders of Agnimanta and Mustaka were taken in equal quantity. The mixture of these two powders was given seven Bhavanas of Gomutra and at the end Eranda Patra Kshara was added to it. Sixteen parts of Gomutra Bhavita Agnimanta and Mustaka was added to the one part of Eranda Patra Kshara. This compound was filled in the capsules.

Duration of treatment
Duration of treatment for both the groups was 7 weeks.

Criteria of assessment
The effect of therapy was assessed on the basis of the following subjective as well as objective criteria.

Subjective criteria
A multidimensional scoring pattern was adopted for the sign and symptoms of Sthaulya mentioned in Ayurvedic texts. The score of symptom was assessed before and after the treatment and statistical analysis was undertaken. Apart from cardinal sign and symptom other signs and symptoms were also assessed. This assessment was done before starting the treatment and thereafter every week till completion of seven week course of therapy. The paired ‘t’ test was applied for the statistical analysis of the results. Moreover assessment of Dosha, Dushya, Srota asa based on their dominant symptoms was also carried out.
Objective criteria
For objective criteria above mentioned parameters mentioned under the heading of investigations and examination and tests were taken into consideration.

Assessment of overall effect of the therapy
For the overall assessment of the therapy following eight categories were taken into consideration:

1. Complete remission: 100% relief in the signs and symptoms, along with reduction in body weight up to normal range, for that particular height in comparison of age, was considered as complete remission.

2. Marked improvement: More than 75% improvement noted in signs and symptoms, along with more than 75% weight reduction, was considered as markedly improved.

3. Moderate improvement: Fifty to 75% improvement was noted in the sign and symptoms along with more then 50% weight reduction was considered as moderate improvement.

4. Improvement: If 25-50% improvement was noted in the sign and symptoms along with more then 25% weight reduction, then it was considered as improvement.

5. Slight improvement: Less than 25% relief in sign and symptoms along with less than 25% weight reduction was considered as slight improvement.

6. Unchanged: No effect in sign and symptoms along with no change in weight was considered as unchanged.

7. Deterioration: Increase in signs and symptoms or appearance of new symptoms or increase in weight was considered as deterioration.

8. Change of score: If improvement was noted in sign and symptoms, but no improvement or mild increase of weight was recorded, then one step down improvement was assigned. Same was followed vice-versa.

Follow-up study
After completion of due course of treatment, all the patients were asked to report for follow-up study for the period of 2 months. In follow-up study statistical changes in body weight, chest circumference, hip circumference, abdomen circumference, abdomen skin fold measurement (SFM) and hip SFM were observed.

Observations
In the present series of 83 patients of Sthaulya (obesity), maximum number of patients were in the age group of 21-50 years (74.69%), female (80.72%), Hindu by religion (65.1%), married (84.34%), belonging to lower middle socioeconomic class (51.81%) and were from urban habitat (98.8%).

In this series maximum number of patients were of Kapha-Vata Prakriti (50.60%) followed by Kapha-Pitta Prakriti (49.39%). The 50.60% patients of this series were vegetarian, 69.88% were having habit of Adhyayana, 92.77% patients were doing sedentary work, 98.79% were not doing exercise at all, 84.34% patients were having sound sleep and 69.88% were jolly in nature.

Majority of the patients in this series i.e., 93.97% each were taking Guru Guna and Shlesma Guna dominant diet, 83.13% patients were satisfied only after ingestion of 50% more than their routine diet requirement and 43.37% of the patients were taking food 3-4 times in a day.

In this series all the patients were having the symptoms of Sphika Chalavta (100%), Anga Gaurava (100%), Anga Shaitilya (100%) and Ati Kshudha (100%). Other signs and symptoms observed were Atipipasa (93.97%), Daurbalya (92.77%), Ayasena Shvasa (91.6%), Utsahahani (92.77%), Svedabaddha (87.95%), Medavatikya (84.34%), Gatra Sada (98.3) and Udara Chalavta (84.33%).

Main Srotodushti observed in patients of this series were Medovaha (100%), Rasavaha (98.79%), Udakavaha (97.59%), Mautjavaha (84.54%), Pranavaha (90.36%), Svedavaha (87.95%), Annavaha (78.31%), Mutravaha (62.65%) and Parshvaha (60.24%).

Maximum numbers of the patients were having Body weight in the range of 71-90 kg (60.24%) and BMI between 31 and 36 (50.60%). Maximum number of the patients i.e., 43.37% had 11-20 kg more weight than ideal body weight followed by 30.12% patients having 21-30 kg more weight than ideal body weight and 48.19% patients were suffering from Sthaulya from 5.1 to 10 years.

In this series maximum number of patients were having cholesterol in the range of 151-200 mg/dl (54.2%), serum triglyceride in the range of 101-150 (30.12%), HDL in the range of 41-50 (37.25), LDL more than 150 (77.1%) and VLDL in the range of 21-30 (38.55%).

Effects of Agnimanthadi compound
Agnimathadi compound provided statistically highly significant reduction of 2.14% in the body weight and 1.86% in BMI [Table 1]. As shown in Table 2 and Figure 1, it provided statistically highly significant relief in Utsaha Hani (50.58%), Daurbalyata (28.41%), Anga Gaurava (25.67%), Nindradhikya (23.88%), Gatra Sada (22.05%) and Aayasena Shvasa (19.4%).

It provided statistically highly significantly reduction of 2.43% in increased pulse rate [Table 3], 4.71% in diastolic blood pressure [Table 4], 9.56% in serum cholesterol [Table 5], 4.98% in walking time [Table 6] and of 0.77% in total SFM [Table 7].

It significantly reduced the systolic blood pressure by 1.68% [Table 8], the circumferences of Mid-arm by 2.70%, forearm by 2.70%, mid thigh by 1.91%, chest by 1.11%, abdomen by 1% and hip by 1% [Table 9 and Figure 2].

It provided statistically highly significant relief of 53.61% in Sroto

| Table 1: Comparison of the effects of therapies on body weight and BMI of 68 patients of Sthaulya |
|-----------------------------------------|-----------------|-----------------|---------|-------|----------|---------|------|----|
| Group of treatment | Mean | % of reduction | SD (±) | SE (±) | t | P |
|---------------------|------|-----------------|--------|--------|---|---|
|                      | BT   | AT             |        |        |   |   |
| Body Weight         | C-Gr.| 79.6           | 79.24  | 0.45   | 1.42 | 0.26 | 1.38 | >0.05 |
|                     | A-Gr.| 80.80          | 79.07  | 2.14   | 1.92 | 0.31 | 5.55 | <0.001|
| BMI                 | C-Gr.| 32.84          | 32.73  | 0.33   | 0.59 | 0.11 | 1.1  | >0.05 |
|                     | A-Gr.| 32.48          | 31.77  | 1.86   | 0.78 | 0.13 | 5.38 | <0.001|

C-Gr. - Control group, A-Gr. - Agnimathadi compound group.
Table 2: Effect of therapies on the symptoms of Sthaulya

| Symptoms          | Mean       | % of relief | SD (±)  | SE (±) | t      | P     |
|-------------------|------------|-------------|---------|--------|--------|-------|
| Ayasena Shvasa    | 1.34       | 1.08        | 19.40   | 0.50   | 0.081  | 3.21  | <0.01 |
| Utsaha Hani       | 1.21       | 0.84        | 30.58   | 0.54   | 0.088  | 4.2   | <0.001|
| Daurbalyata       | 1.76       | 1.26        | 28.41   | 0.56   | 0.09   | 5.55  | <0.001|
| Nidra Adhikya     | 1.34       | 1.02        | 23.88   | 0.47   | 0.078  | 4.08  | <0.001|
| Sveda Abadha      | 1.60       | 1.47        | 8.12    | 0.34   | 0.055  | 2.36  | <0.05 |
| Snigdha-angata    | 0.87       | 0.79        | 9.19    | 0.27   | 0.044  | 1.82  | >0.05 |
| Angagaurava       | 1.87       | 1.39        | 25.67   | 0.51   | 0.083  | 5.66  | <0.001|
| Atipipasa         | 1.55       | 1.47        | 5.16    | 0.027  | 0.044  | 1.82  | >0.05 |
| Ati-Kshudha       | 4.29       | 4.26        | 0.70    | 0.16   | 0.026  | 1     | >0.05 |
| Gatra-Sada        | 1.95       | 1.52        | 22.05   | 0.50   | 0.081  | 5.18  | <0.001|
| Anga Shathilaya   | 2.18       | 2.10        | 3.67    | 0.27   | 0.044  | 1.82  | >0.05 |
| Ati Mutrata       | 0.63       | 0.79        | ~25.39  | 0.37   | 0.060  | 2.66  | <0.02 |

Table 3: Comparison of the effects of therapies on pulse rate of 68 patients of Sthaulya

| Groups of treatment | Mean | % of reduction | SD (±)  | SE (±) | t      | P     |
|---------------------|------|----------------|---------|--------|--------|-------|
| Control             | 88.2 | 87.76          | 0.50    | 2.84   | 0.52   | 0.83  | >0.05 |
| Agnimanthadi compound | 88.71 | 86.55          | 2.43    | 3.43   | 0.56   | 3.86  | <0.001|

Table 4: Comparison of the effects of therapies on diastolic blood pressure of 68 patients of Sthaulya

| Groups of treatment | Mean | % of reduction | SD (±)  | SE (±) | t      | P     |
|---------------------|------|----------------|---------|--------|--------|-------|
| Control             | 82.8 | 80.93          | 2.26    | 2.72   | 0.50   | 3.74  | <0.001|
| Agnimanthadi compound | 87.21 | 83.10          | 4.71    | 5.58   | 0.90   | 4.55  | <0.001|

Dushti symptoms of Annavaha and of 33.80% in Rasavaha Srotasa [Table 10]. It also significantly increased the symptom of Ati Mutrata by 25.39% [Table 2] which showed its diuretic effect.

The overall effect showed that Agnimanthadi compound provided moderate relief in 5.26%, Improvement in 13.16 and, slight improvement in 63.16% patients. In this group 5.26% patients remained Unchanged and 5.26% patients were further deteriorated [Table 11].

In follow-up study [Table 12], highly significant reduction (P < 0.001) in body weight was observed in one month follow-up [Table 13]. But, this significant reduction was not sustained in the second month of follow-up study [Table 13].

Effect of control group

Placebo in control group provided slight reduction in body weight and BMI but both the findings were not statistically significant [Table 1]. It provided significant relief in the symptoms of Daurbalyata (31.50%), Utsaha Hani (28.57%), Ayasena Shvasa (23.1%), Anga Gaurava (19.11%) and Nidradhikya (11.96%) as shown in Table 14. It significantly reduced diastolic blood pressure by 2.26%
Table 5: Comparison of the effects of therapies on lipid profile of 68 patients of *Sthaulya*

| Lipid profile            | Group of treatment | Mean         | % of change | SD (±)     | SE (±)     | t    | P     |
|--------------------------|--------------------|--------------|-------------|------------|------------|------|-------|
| Serum cholesterol        | C-Gr.              | 188.07       | 5.06        | 38.61      | 7.58       | 1.25 | >0.05 |
|                          | A-Gr.              | 182.3        | 9.56        | 27.49      | 4.46       | 3.90 | <0.001|
| Serum triglyceride       | C-Gr.              | 178.19       | 6.59        | 71.57      | 14.06      | 0.83 | >0.05 |
|                          | A-Gr.              | 142.2        | 23.78       | 119.85     | 19.66      | 1.72 | >0.05 |
| Serum HDL                | C-Gr.              | 39.39        | -5.61       | 9.64       | 21.04      | 0.10 | >0.05 |
|                          | A-Gr.              | 40.67        | 0.44        | 12.07      | 1.96       | 0.09 | >0.05 |
| Serum LDL                | C-Gr.              | 106.31       | 10.77       | 36.66      | 7.65       | 1.56 | >0.05 |
|                          | A-Gr.              | 113.2        | 9.36        | 27.35      | 4.44       | 2.36 | <0.02 |
| Serum VLDL               | C-Gr.              | 35.64        | 6.59        | 14.31      | 2.81       | 0.84 | >0.05 |
|                          | A-Gr.              | 28.45        | 23.80       | 23.97      | 3.89       | 1.74 | >0.05 |
| Serum TC/HDLC ratio      | C-Gr.              | 5.18         | 15.06       | 1.98       | 0.36       | 14.39| <0.001|
|                          | A-Gr.              | 4.73         | 11.20       | 1.50       | 0.24       | 2.23 | <0.02 |
| Serum LDLC/HDLC ratio    | C-Gr.              | 2.96         | 16.55       | 1.42       | 0.26       | 11.38| <0.001|
|                          | A-Gr.              | 2.92         | 9.25        | 1.27       | 0.20       | 1.4  | >0.05 |

C-Gr. - Control group, A-Gr. - Agnimanthadi compound group, HDL - High density lipoprotein, LDL - Low density lipoprotein, VLDL - Very Low-Density Lipoprotein, TC/HDLC - Total cholesterol/High density lipoprotein cholesterol ratio, LDLC/HDLC - Low density lipoprotein cholesterol/High density lipoprotein cholesterol ratio

Table 6: Comparison of the effects of therapies on walking time of 68 patients of *Sthaulya*

| Groups of treatment | Mean | % of change | SD (±) | SE (±) | t    | P  |
|---------------------|------|-------------|--------|--------|------|----|
| C-Gr.               | 33.2 | 1.2         | 1.87   | 0.34   | 1.18| >0.05|
| A-Gr.               | 32.1 | 4.98        | 2.38   | 0.39   | 4.10| <0.001|

C-Gr. - Control group, A-Gr. - Agnimanthadi compound group

Table 7: Comparison of the effects of therapies on various SFM of 68 patients of *Sthaulya*

| Group of treatment | Mean | % of reduction | SD (±) | SE (±) | t    | P  |
|-------------------|------|----------------|--------|--------|------|----|
| Waist/Hip ratio   | C-Gr. | 0.99 | 0.99 | 0 | 0.011 | 0.002 | 0.35 | >0.05|
|                   | A-Gr. | 0.95 | 0.94 | 1.05 | 0.011 | 0.0018 | 1.68 | >0.05|
| Biceps SFM        | C-Gr. | 4.12 | 4.12 | 0 | 0.074 | 0.030 | 0 | -|
|                   | A-Gr. | 4.24 | 4.20 | 0.94 | 0.095 | 0.015 | 2.8 | <0.01|
| Triceps SFM       | C-Gr. | 4.14 | 4.14 | 0 | 0.095 | 0.017 | 0 | -|
|                   | A-Gr. | 4.33 | 4.28 | 0.92 | 0.083 | 0.013 | 3.23 | <0.01|
| Abdomen SFM       | C-Gr. | 6.79 | 6.78 | 0.15 | 0.102 | 0.018 | 0.94 | >0.05|
|                   | A-Gr. | 6.56 | 6.51 | 0.76 | 0.083 | 0.013 | 2.23 | <0.05|
| Supra iliac SFM   | C-Gr. | 5.50 | 5.48 | 0.36 | 00087 | 0.016 | 1.25 | >0.10|
|                   | A-Gr. | 5.27 | 5.24 | 0.57 | 0.075 | 0.012 | 3.25 | <0.01|
| Mid thigh SFM     | C-Gr. | 5.42 | 5.34 | 1.48 | 0.095 | 0.017 | 1 | >0.10|
|                   | A-Gr. | 5.55 | 5.50 | 0.90 | 0.12 | 0.019 | 2.21 | <0.05|
| Total SFM         | C-Gr. | 25.97 | 25.92 | 0.19 | 0.21 | 0.038 | 1.39 | >0.10|
|                   | A-Gr. | 25.96 | 25.76 | 0.77 | 0.21 | 0.034 | 5.59 | <0.001|

C-Gr. - Control group, A-Gr. - Agnimanthadi compound group

Table 8: Comparison of the effects of therapies on systolic blood pressure of 68 patients of *Sthaulya*

| Groups of treatment | Mean | % of reduction | SD (±) | SE (±) | t    | P  |
|---------------------|------|----------------|--------|--------|------|----|
| Control             | 121.8| -0.08          | 3.67   | 0.67   | -0.19| >0.05|
| Agnimanthadi        | 125.58| 1.68          | 5.88   | 0.95   | 2.21 | <0.05|
Table 9: Comparison of the effects of therapies on various of 68 patients of Sthaulya

| Sroto Dushti                        | Group of treatment | Mean        | % of reduction | SD (±)  | SE (±)  | t     | P      |
|-------------------------------------|-------------------|-------------|----------------|---------|---------|-------|--------|
| Chest                               | C-Gr.             | BT 40.31    | 0.64           | 0.53    | 0.097   | 0.27  | >0.05  |
|                                     | A-Gr.             | AT 40.05    |                | 0.53    | 0.097   | 0.27  | >0.05  |
| Abdomen                             | C-Gr.             | BT 39.34    | 0.46           | 0.50    | 0.091   | 1.87  | <0.001 |
|                                     | A-Gr.             | AT 39.16    |                | 0.50    | 0.091   | 1.87  | <0.001 |
| Hip circumference                   | C-Gr.             | BT 42.61    | 1              | 0.52    | 0.084   | 5.24  | <0.001 |
|                                     | A-Gr.             | AT 42.18    |                | 0.52    | 0.084   | 5.24  | <0.001 |
| Mid arm                             | C-Gr.             | BT 44.55    | 0.20           | 0.76    | 0.14    | 0.66  | >0.05  |
|                                     | A-Gr.             | AT 44.46    |                | 0.76    | 0.14    | 0.66  | >0.05  |
| Forearm                             | C-Gr.             | BT 43.88    | 1              | 0.48    | 0.078   | 5.64  | <0.001 |
|                                     | A-Gr.             | AT 43.44    |                | 0.48    | 0.078   | 5.64  | <0.001 |
| Mid thigh                           | C-Gr.             | BT 12.13    | 0.41           | 0.53    | 0.097   | 0.48  | >0.10  |
|                                     | A-Gr.             | AT 12.08    |                | 0.53    | 0.097   | 0.48  | >0.10  |
| Circumference                       | A-Gr.             | BT 41.54    | 0.41           | 0.53    | 0.097   | 0.48  | >0.10  |
|                                     | A-Gr.             | AT 41.08    |                | 0.53    | 0.097   | 0.48  | >0.10  |
| Abdomen                             | A-Gr.             | BT 39.16    | 0.46           | 0.50    | 0.091   | 1.87  | <0.001 |
|                                     | A-Gr.             | AT 39.05    |                | 0.50    | 0.091   | 1.87  | <0.001 |
| Hip circumference                   | A-Gr.             | BT 42.18    | 1              | 0.52    | 0.084   | 5.24  | <0.001 |
|                                     | A-Gr.             | AT 42.18    |                | 0.52    | 0.084   | 5.24  | <0.001 |
| Mid arm                             | A-Gr.             | BT 44.46    | 0.20           | 0.76    | 0.14    | 0.66  | >0.05  |
|                                     | A-Gr.             | AT 44.46    |                | 0.76    | 0.14    | 0.66  | >0.05  |

C-Gr. - Control group, A-Gr. - Agnimanthadi compound group

Table 10: Comparison of the effects of therapies on Sroto Dushti of 68 patients of Sthaulya

| Sroto Dushti                        | Group of treatment | Mean        | % of relief | SD (±)  | SE (±)  | t     | P      |
|-------------------------------------|-------------------|-------------|-------------|---------|---------|-------|--------|
| Annavaha Sroto Dushti               | C-Gr.             | BT 0.83     | 3.61        | 0.32    | 0.058   | 0.57  | >0.05  |
|                                     | A-Gr.             | AT 0.86     |             | 0.32    | 0.058   | 0.57  | >0.05  |
| Rasavaha Sroto Dushti               | C-Gr.             | BT 3.67     | 23.70       | 1.22    | 0.22    | 3.95  | <0.001 |
|                                     | A-Gr.             | AT 2.8      |             | 1.22    | 0.22    | 3.95  | <0.001 |
| Pranavaha                           | C-Gr.             | BT 0.97     | 20.62       | 0.48    | 0.088   | 2.27  | <0.05  |
|                                     | A-Gr.             | AT 0.77     |             | 0.48    | 0.088   | 2.27  | <0.05  |
| Sroto Dushti                        | C-Gr.             | BT 0.95     | 16.84       | 0.37    | 0.060   | 2.66  | <0.02  |
|                                     | A-Gr.             | AT 0.79     |             | 0.37    | 0.060   | 2.66  | <0.02  |
| Udakavaha                           | C-Gr.             | BT 1.03     | 0           | 0       | 0       | 0     | 0      |
|                                     | A-Gr.             | AT 1.03     |             | 0       | 0       | 0     | 0      |
| Sroto Dushti                        | C-Gr.             | BT 0.92     | 3.26        | 0.16    | 0.025   | 1.04  | >0.05  |
|                                     | A-Gr.             | AT 0.89     |             | 0.16    | 0.025   | 1.04  | >0.05  |
| Svedavaha                           | C-Gr.             | BT 0.97     | 7.22        | 0.25    | 0.046   | 1.46  | <0.05  |
|                                     | A-Gr.             | AT 0.9      |             | 0.25    | 0.046   | 1.46  | <0.05  |
| Sroto Dushti                        | C-Gr.             | BT 0.84     | 3.57        | 0.16    | 0.025   | 1.04  | >0.05  |
|                                     | A-Gr.             | AT 0.81     |             | 0.16    | 0.025   | 1.04  | >0.05  |
| Mutravaha                           | C-Gr.             | BT 0.53     | 15.15       | 0.31    | 0.050   | 2     | >0.05  |
|                                     | A-Gr.             | AT 0.76     |             | 0.31    | 0.050   | 2     | >0.05  |
| Sroto Dushti                        | C-Gr.             | BT 0.66     | −15.15      | 0.31    | 0.050   | 2     | >0.05  |
|                                     | A-Gr.             | AT 0.6      |             | 0.31    | 0.050   | 2     | >0.05  |
| Punishavaha Sroto                   | C-Gr.             | BT 0.6      | 0          | 0       | 0       | 0     | 0      |
|                                     | A-Gr.             | AT 0.6      |             | 0       | 0       | 0     | 0      |
| Dushti                              | C-Gr.             | BT 0.37     | 21.62       | 0.27    | 0.044   | 1.82  | >0.05  |
|                                     | A-Gr.             | AT 0.29     |             | 0.27    | 0.044   | 1.82  | >0.05  |

C-Gr. - Control group, A-Gr. - Agnimanthadi compound group

Table 11: Overall effect of Agnimanthadi compound group on 38 patients of Sthaulya

| Result                            | No. of patients | %    |
|-----------------------------------|-----------------|------|
| Complete remission                | -               | -    |
| Marked improvement                | -               | -    |
| Moderate improvement              | 2               | 5.26 |
| Improvement                       | 5               | 13.16|
| Slight improvement               | 24              | 63.16|
| Unchanged                         | 2               | 5.26 |
| Deterioration                     | 5               | 13.16|

Table 12: Follow-up observation in the patients of Sthaulya

| Months of follow-up after treatment | No. of patients in group |
|-------------------------------------|--------------------------|
|                                     | C group                  | A group                  |
| 1 month                             | 23                       | 25                       | 48                        |
| 2 month                             | 14                       | 20                       | 34                        |

Discussion

In the present series, 83 patients fulfilling the criteria for the diagnosis of Sthaulya were selected. Out of which 15 patients had left the treatment at different stages. The remaining 68 patients completed full course of treatment for the period of 7 weeks, out of which 30 patients were in placebo control group and 38 patients were in Agnimanthadi compound group.

Comparison of the results of both the groups showed that Agnimanthadi compound provided better relief to the patients of Sthaulya than control group in the symptoms of Utsaha Hani, Anga Gaurava, Nindradhikya, Gatra Sada, Snigdha Angata
Table 13: Follow-up study of the patients of Sthaulya in Agnimanthadi compound group

| Symptoms                  | Follow-up in months | Mean | SD (±) | SE (±) | t     | P   |
|---------------------------|---------------------|------|--------|--------|-------|-----|
| Body weight               | After 1 month       | 80.21| 80.09  | 0.70   | 0.028 | 4.28| <0.001|
|                           | After 2 months      | 82   | 81.70  | 0.93   | 0.91  | 1.43| >0.10  |
| Chest circumference       | After 1 month       | 41.13| 40.95  | 0.56   | 0.11  | 1.61| >0.10  |
|                           | After 2 months      | 41.53| 41.38  | 0.77   | 0.17  | 0.88| >0.10  |
| Abdomen circumference     | After 1 month       | 42.69| 42.55  | 0.45   | 0.09  | 1.55| >0.10  |
|                           | After 2 months      | 43.24| 43.11  | 0.60   | 0.13  | 1   | >0.10  |

Table 14: Effect of control (placebo) on the sign and symptoms of 30 patients of Sthaulya

| Symptoms                  | Mean | % of relief | SD (±) | SE (±) | t     | P   |
|---------------------------|------|-------------|--------|--------|-------|-----|
| Ayasena Shvasa            | 1.3  | 23.1        | 0.53   | 0.097  | 3.09  | <0.01|
| Utsaha Hani               | 1.4  | 28.57       | 0.56   | 0.10   | 4.0   | <0.001|
| Daurbalya                 | 1.27 | 31.50       | 0.56   | 0.10   | 4.0   | <0.001|
| Nidra Adhikya             | 1.17 | 11.96       | 0.34   | 0.062  | 2.09  | >0.05|
| Sveda Abadha              | 1.43 | 6.99        | 0.40   | 0.073  | 1.37  | >0.05|
| Snigdha-angata            | 0.97 | 7.22        | 0.25   | 0.046  | 1.46  | >0.05|
| Angagaurava               | 1.57 | 19.11       | 0.53   | 0.097  | 3.09  | <0.01|
| Atipipasa                 | 1.43 | 0           | 0      | 0      | 0    | -   |
| Ati-Kshudha               | 4.37 | 0           | 0      | 0      | 0    | -   |
| Gatra-Sada                | 1.77 | 3.95        | 0.25   | 0.046  | 1.46  | >0.10|
| Anga Shathilaya           | 1.87 | 0           | 0      | 0      | 0    | -   |
| Ati Mutrata               | 0.53 | 0           | 0      | 0      | 0    | -   |

Table 15: Overall effect of control group on 30 patients of Sthaulya

| Result                     | No. of patients | %    |
|----------------------------|-----------------|------|
| Complete remission         | 0               | -    |
| Marked improvement         | 0               | -    |
| Moderate improvement       | 0               | -    |
| Improvement                | 10              | 33.33|
| Slight improvement         | 12              | 40   |
| Unchanged                  | 2               | 6.67 |
| Deterioriation             | 6               | 20   |

Comparison of the overall effects of the therapies

Agnimanthadi compound provided better improvement in overall signs and symptoms and laboratory findings related to Sthaulya in comparison to the Control group [Tables 11 and 15] [Figure 3].

The results of the follow-up study showed, highly significant reduction ($P < 0.001$) in body weight in one month follow-up [Table 13]. But, this significant reduction was not sustained in the second month of follow-up study [Table 13]. On the other hand no such effect was noticed in Placebo group at the follow-up study [Table 16].
Agnimanthadi compound comprises of Agnimantha, Mustaka, Eranda Putra Kshara and Gomutra, which are have Dipana, Rachana, Medohara and Kaphaphara actions. Due to these properties of the drugs, Agnimanthadi Compound may have acted on hypo function of Bhutagni which was noticed by its significant effect on Annavaha Srotasa Dushhti and on Utsah Hani and Daurbalyata which indicates it has effect at the level of Bhutagni. Medohara action of these drugs has provided significant effect on all the sign and symptoms of Sthaulya.

### Conclusion

The present placebo controlled clinical study was carried out on the patients of Sthaulya to evaluate the effects of Agnimanthadi compound administered orally in the dose of 2 g three times a day for 7 weeks. On the basis of the results of this study following conclusions may be drawn:

- **Agnimanthadi** compound provided significant relief in the symptoms of Aysena Shvasa, Utsaha Hani, Daurbalyata, Nidra Adhikya, Sveda Abadha, Snigdha Angata, Angagaurava, Atipipasa and Ati-Kshudha.
- **Agnimanthadi** compound significantly reduced the body weight and BMI of the patients of Sthaulya.
- **Agnimanthadi** compound provided significant relief in the Dushti Lakshana of Annavaha Srotasa and Rasavaha Srotasa.
- **Agnimanthadi** compound significantly reduced all the circumferences of fatty parts of the body viz. biceps SFM, triceps SFM, suprailiac SFM and total SFM.
- **Agnimanthadi** compound also significantly improved the walking time and reduced the increased pulse rate and diastolic blood pressure.
- **Agnimanthadi** compound also provided comparatively better relief in serum cholesterol, serum LDL, serum HDLC/LDL ratio [Table 5].

- **Agnimanthadi** compound provided moderate relief in 5.26%, improvement in 13.16% and slight improvement in 63.16% patients. In this group 5.26% patients remained unchanged and 5.26% patients were further deteriorated.
- In most of the cases the beneficial effects of Agnimanthadi compound were better in comparison to the placebo control group.

### Table 16: Follow-up study of the patients of Sthaulya in control group

| Symptoms                  | Follow-up in months | Mean     | SD (±) | SE (±) | t     | P     |
|---------------------------|---------------------|----------|--------|--------|-------|-------|
|                           | BT                  | AT       |        |        |       |       |
| Body weight               | After 1 month       | 78.39    | 78.52  | 0.61   | 0.13  | −1    | >0.10 |
|                           | After 2 months      | 78.08    | 78.36  | 0.99   | 0.26  | −0.75 | >0.10 |
| Chest circumference       | After 1 month       | 40.1     | 40.13  | 0.11   | 0.02  | −1.5  | >0.10 |
|                           | After 2 months      | 40.16    | 40.18  | 0.16   | 0.04  | −0.75 | >0.10 |
| Abdomen circumference     | After 1 month       | 39.2     | 39.22  | 0.13   | 0.03  | −0.66 | >0.10 |
|                           | After 2 months      | 38.86    | 38.91  | 0.14   | 0.04  | −1.25 | >0.10 |
| Hip circumference         | After 1 month       | 44.23    | 44.29  | 0.17   | 0.03  | −0.66 | >0.10 |
|                           | After 2 months      | 45.06    | 45.21  | 0.24   | 0.06  | −1.33 | >0.10 |
| Abdomen SFM               | After 1 month       | 6.7      | 6.71   | 0.05   | 0.01  | −1    | >0.10 |
|                           | After 2 months      | 6.56     | 6.58   | 0.06   | 0.01  | −2    | >0.05 |
| Hip SFM                   | After 1 month       | 5.91     | 5.92   | 0.05   | 0.01  | −0.9  | >0.10 |
|                           | After 2 months      | 5.76     | 5.77   | 0.07   | 0.02  | −0.5  | >0.10 |

SFM – Skin fold measurement

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हिन्दी सारांश
स्थूल्य की चिकित्सा में अग्निमन्थादि योग का क्लिनिकल अध्ययन
रविकांत गोयल, मनदीप कौर, एच. एम. चन्द्रोता

विश्व की जनसंख्या में स्थूल्य रोग इतना प्रचलित हो गया है कि इसने घोषणा अभावजन्य तथा संक्रामित व्याधियों को भी पीछे छोड़ दिया है। स्थूल्य, स्वास्थ्य जनक अनेक समस्याओं को उत्पन्न करता है, इसलिए इस शोध में अग्निमन्थादि योग का प्रयोग स्थूल्य की चिकित्सा में किया गया है। इस गवेशण में स्थूल्य के कुल 83 रूग्णों को पंजीकृत किया गया तथा सभी को 2 समूहों में सरल यथार्थ पद्धति से बोटा गया। जिनमें से 55 रूग्णों ने चिकित्सा की अवधि पूर्ण नहीं की। समूह A में 38 रूग्णों को अग्निमन्थादि योग आयोंर प्रयोगार्थ 8 केप्स्यूल (500मि.ग्रा.) दिन में 3 बार भोजन से पहले दिया गया, जबकि समूह B में 30 रूग्णों को प्लेसिबो(स्टार्चयुक्त) आयोंर प्रयोगार्थ 2 केप्स्यूल (500 मि.ग्रा.) दिन में 3 बार भोजन से पहले दिया गया। दोनों समूहों की चिकित्सा की अवधि 7 समाह थी। दोनों समूहों की औषधियों के प्रभाव का निरीक्षण करने पर यह ज्ञात होता है कि अग्निमन्थादि योग प्लेसिबो की तुलना में भारहानि, बी.एम.आई. और अन्य चिन्हों तथा लक्षणों को कम करने में उत्तम रूप से प्रभावकारी है।