## CLINICAL STUDY ON GUDUCHI (*TINOSPORA CORDIFOLIA* WILLD.) AND MUSTAK (*CYPERUS ROTUNDUS* LINN.) IN STHOULYA WITH SPECIAL REFERENCE TO OVERWEIGHT

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## ABSTRACT

In recent time, due to sedentary habits of modern life style with various push button facilities, lack of physical exercise and stress at the workplace, we have overlooked our principles like Dincharya, Ritucharya, Achararasayana etc. resulting occurrence of several lifestyle related health problems including Obesity i.e. Sthoulya. This condition of obesity can be diagnosed earlier i.e. Overweight. A single centre, randomized open label triple arm (n-20) clinical trial (60 days total duration) has been conducted in order to evaluate the action of Guduchi (*Tinospora cordifolia* Willd) churna in group A, Mustak (*Cyperus rotundus* Linn.) churna in group B and combined form of Guduchi Mustak churna in group C patients of Sthoulya i.e. Overweight. Maximum percentage result was observed in group C in all parameters.

**Keywords:** Obesity, Overweight, Sthoulya, Guduchi, Mustak

## INTRODUCTION

In recent time, due to sedentary habits of modern life style with various push button facilities, automation, lack of physical exercise and stress at the workplace, we have overlooked these principles of living life and mere following of western culture and food habits in day to day activities resulting occurrence of several lifestyle related health problems including Obesity i.e. Sthoulya. This condition of obesity can be diagnosed earlier i.e. Overweight. Overweight is a premonitory symptom of Obesity[1] i.e. Sthoulya. The term "Overweight" represents excess body weight in relation to height. It is often expressed in terms of Body Mass Index (BMI). A BMI of 25 or more indicates overweight which leads to obesity. The WHO designations include the following: Grade 1 overweight (commonly called overweight) - BMI of 25-29.9 kg/m². Grade 2 overweight (commonly called obesity) - BMI of 30-39.9 kg/m². Grade 3 overweight (commonly called severe or morbid obesity) - BMI greater than or equal to 40 kg/m².

Major Life style disorder like Sthoulya i.e. Overweight has emerged as big challenge for the health practitioners worldwide. Obesity is classified as a disease in 2013 by American Medical Association. To aware the people about the disease; World Obesity day is celebrated on 11th October, every year. According to the different surveys, obesity has reached epidemic proportions in India in the 21st century, affecting about 120 million of the country's urban population. India ranks amongst top ten obese nations, with morbid obesity affecting 5% of the country's population[2]. In Northern India obesity was most prevalent in urban populations (male - 5.5%, female - 12.6%), followed by the urban slums (male - 1.9%, female -7.2%)[3].

Ayurveda, the ancient science of life, regained its eminence and popularity in recent era. Hereafter, the society is looking to this discipline for its contribution to the field of such life style disorders i.e. Sthoulya. In CharakaSamhita[4] - Sthoulya is described as "Ashtauninditiya Sharira (eight censurable persons)". In the context of body these persons are considered to be despicable or unappreciable for their body. Sthoulya is a condition wherein there will be Sharira Ayathoupchaya[5] associated with abnormal increase of Medodhatu and also described as Santarpanjanit Roga[6]. In Sushruta Samhita (Sutrasthan chapter 15), Sthoulya is mentioned as Rasanimittam[7]. It has been evidenced that Sthoulya is a worst condition of a particular person[8].

Over last three decades, despite several public health efforts, none of the country has reported decreasing rate of obesity. It reflects that the solutions for the problem of obesity remain elusive. The modern management of Obesity with synthetic drugs, surgeries has many residual effects associated with it. Natural way to address Sthoulya has been mentioned in Ayurveda. Today, there is urgent need to find out the drugs which are cost effective, easy to available and easy to administer. Therefore, keeping in view above facts and to get a way through the burning issue of overweight, It was expected that proposed drugs Guduchi (*Tinospora cordifolia* Willd) and Mustak (*Cyperus rotundus* Linn.) check the pathogenesis of Sthoulya and act on the basic root cause of the disease and arrest the progress of the disease Sthoulya i.e. overweight effectively owing to its inherent properties. In Charak samhita sutrasthan 21 verses 22 both of these drugs are described to cure Sthoulya.

As guduchi is abundantly available at very low cost and its medohara effect has been stated by dhanvantarinighantu[9]. Due to its multifaceted pharmacological actions. It is also getting honour of Rashtriya aushadhi. Mustak is also available at low cost than other anti-obesity drugs and described in Lekhaneeyamahakashaya[10] (drugs acting as scraping agents) which helps in removal of morbid accumulation and sthoulyahar action.

## MATERIAL AND METHODS

It was single centre, randomized, open label, interventional type, triple Arm clinical trial. The study was explained clearly to the subject and their signed, written informed consent was taken before starting the trial. A total of 60 subjects completed the trial out of 63 subjects registered for the trial. Subjects were randomly assigned in three groups 20 in each group. Trial was conducted after approval of IEC of National Institute of Ayurveda with approval no. IEC/ ACA/ 2017/ 08. The trial was also registered in CTRI with registration no. CTRI/2018/08/015160. The trial drugs Guduchi stem and Mustak's rhizomes were used individually along with combination of both in the form of Churna.

### Grouping, dose, duration of treatment

A dose of 3 gm twice a day was given with lukewarm water 1 Hour before Principle Meal. All the patients were followed up-once in 2 weeks regularly for medicines in each group at interval of every 15 days. Total duration of treatment was 60 days.

**Table1: Distribution of Patients with dose, duration and Bhaishjaya Kaal**

| Group | No of Patients | Dose | Anupan | Duration of Therapy | Bhaishjaya Kaal |
|---|---|---|---|---|---|
| A. Guduchi Churna | 20 | 3 gm BD | Lukewarm Water | 60 days | 1 Hour Before Principle Meal |
| B. Mustak Churna | 20 | 3 gm BD | Lukewarm Water | 60 days | 1 Hour Before Principle Meal |
| C. Churna of Guduchi and Mustak | 20 | 3 gm BD | Lukewarm Water | 60 days | 1 Hour Before Principle Meal |

### Inclusion criteria

- Patients from either sex with classical sign and symptoms of Sthoulya.
- Patients of age group 16 - 60 years.
- Patients with BMI more than 25 $Kg/m^2$ - 29.9 $Kg/m^2$
- Waist to Hip ratio (Males > 0.90 and Females > 0.80) according to WHO.

### Exclusion criteria

- Patients below 16 and above 60 years of age,
- Patients having major systemic disorders or other illnesses such as Hypothyroidism, Cushing syndrome, Hypersensitivity and Diabetes, which interfere with the present study.
- Patients having any hereditary disposition
- Patients with serious disease limiting life expectancy.
- Pregnancy and lactating mother.

### Pre-treatment evaluation

After preliminary registration, all the patients were subjected to record their detail case history and physical examination as per following schedule.

- Chief Complaints with Duration
- History of present illness
- History of past illness
- Family history of relevant disease
- Menstrual history (in case of females)
- Physical examination

In general examination, general condition, sensorium, gait, pulse rate, blood pressure, respiration rate, height, weight, body temperature, pallor, cyanosis, icterus, edema, clubbing etc. were examined.

Systemic examination was conducted for detailed checkup of respiratory, cardiovascular, central nervous system, gastrointestinal, musculo-skeletal and genitourinary system to exclude any complications of Obesity or any other abnormalities.

### Biochemical investigations

Lipid profile was done before treatment (BT) and after treatment (AT) to access the effect of test drug.

### Anthropometric examination

- **Height:** The patient's height was recorded in centimeter from the height stand.
- **Weight:** The weight of the patients in the normal clothing was taken in kilogram using a standard weighing machine.
- **Circumferences:** Mid-arm and Mid-thigh, waist and hip circumferences were recorded using a measuring tape.

Body Mass Index and Waist hip ratio were calculated using the above data is as follows

- **Body Mass Index** = Weight (in Kg)÷ (Height)$^2$ (in m$^2$)
- **Waist hip ratio** = Waist circumference (in cm) ÷ Hip circumference (in cm)

### Parameters of assessment

Assessment were done under the headings

1. Subjective
2. Objective

### Subjective assessment

This completely depended upon symptomatology and grades depended on symptoms as stated in text and told by patient. In each patients were assessed for the subjective parameters. The clinical grades were decided as follows-

**Table 2: Subjective parameter of Sthoulya patients and their grading**

| Subjective parameter | Grade |
|---|---|
| **Javoparodh (Sluggishness/Inability to do work)** | |
| No Alasya (doing work satisfactory with) proper vigor in time | 0 |
| Doing work with desire with initiation late in time | 1 |
| Doing work without desire with lot of mental pressure and late in time | 2 |
| Not starting any work with own responsibility, doing little work very slowly | 3 |
| Does not have any initiation and not wants to work even after pressure | 4 |
| **Daurgandhya (Foetid body odor)** | |
| Absence of bad smell | 0 |
| Occasional bad smell in the body removed after bathing | 1 |
| Persistent bad smell limited to close areas, difficult to suppress by deodorants | 2 |
| Persistent bad smell felt from long distance not suppressed by deodorants | 3 |
| Persistent bad smell felt from long distance even intolerable to the patient himself | 4 |
| **Swedaabaadha (Excessive sweating)** | |
| Sweating after heavy work and fast movement or in hot season | 0 |
| Profuse sweating after moderate work and movement | 1 |
| Sweating after little work and movement | 2 |
| Profuse sweating after little work and movement | 3 |
| Sweating even at rest or in cold season | 4 |
| **Kshudhatimatra (Excessive hunger)** | |
| Normal diet with lunch and Dinner- | 0 |
| Morning breakfast with lunch and dinner | 1 |
| Supplementary food with above mentioned articles | 2 |
| **Pipasaatiyog (Excessive thirst)** | |
| Up to 1 to 1.5 liters of intake per day | 0 |
| Up to 1-liter excess intake of water | 1 |
| 1 to 2-liter excess intake of water | 2 |
| 2 to 3-liter excess intake of water | **3** |
| More than 3-liter intake of water[11] | 4 |

**Objective assessment**

This was done as follow

**Anthropometric examinations**

Including Body weight, Body Mass Index, Waist to Hip ratio, Mid arm Circumference, Mid-thigh Circumference were done.

**Lipid profile**

It was done before treatment and after the completion of Trial.

**RESULT**

All the Results were calculated by using Software: In Stat Graph Pad.

**Intra group comparison**

- For Nonparametric Data **Wilcoxon signed ranks test** was used.
- For Parametric Data **Paired 't' Test** was used and results were calculated.

**Inter group comparison**

- For nonparametric variables, **Kruskal-Wallis Test** and **Dunn's Multiple Comparisons Test** (Post Test) was used.

- For the parametric data, **ANOVA test** was used, and results were calculated.

**Effect of therapy on subjective parameter**

In Intra group comparison all three groups have shown statistically significant results. On intergroup comparison statistically significant result were found in subjective parameter like Daurgandhya, Swedabadha while Javoprodh, Kshudhatimatra, Pipasaatiyog have shown insignificant changes. Maximum percentage of relief was observed in group C in all subjective parameters besides Swedabadha, In Swedabadha Group B has shown maximum percentage relief. On intergroup comparison, by the post test, group B Vs group C have shown in-significant difference. Thus both the groups have similar effect.

**Effect of therapy on objective parameter**

Statistically significant result was found in body weight, Body Mass Index, mid-arm and mid-thigh circumference in all three groups. But in-significant result was found in waist to hip ratio. Maximum percentagewise result was found in group C than other two groups.

In lipid profile, all three groups shown significant results in all parameters. Maximum percentagewise result was found in group B in parameters like low density lipoprotein (LDL), high density lipoprotein (HDL) and Serum Triglycerides. In group C

maximum percentagewise result was found in total cholesterol and Very low density lipoprotein (VLDL).

In intergroup comparison by one-way analysis of variance test (ANOVA test) there was highly significant result (P < .0001) was found in Parameters like body weight, B.M.I., total cholesterol and significant result (p < 0.05) was found in parameters like mid-arm, mid-thigh circumference, HDL, LDL cholesterol. But in-

significant result was found in parameters like waist to hip ratio and VLDL cholesterol.

In Intergroup comparison by "Tukey-Kramer multiple comparison test" for parametric comparison group B vs C was found statistically in-significant in all objective parameters that mean both group therapies had similar results.

**Table 3: Overall percentage result in subjective parameters in all 3 groups**

| Subjective parameters | % Relief in Group A | % Relief in Group B | % Relief in Group C |
|---|---|---|---|
| Javoprodha | 35.90 | 51.35 | 55.56 |
| Daurgandhya | 41.94 | 66.67 | 70.00 |
| Swedabadha | 39.13 | 76.47 | 61.70 |
| Kshudhatimatra | 42.86 | 69.57 | 70.37 |
| Pipasaatiyog | 54.55 | 60.00 | 62.96 |

**Table 4: Result in Inter group comparison by" Kruskal-Wallis test"**

| Parameters | Group A | Group B | Group C | P Value | Significant |
|---|---|---|---|---|---|
| Javoprodh | 0.82 | 1.12 | 1.50 | > 0.05 | Ns |
| Daurgandhya | 0.76 | 1.53 | 1.75 | < 0.05 | S |
| Swedabadha | 0.53 | 1.53 | 1.45 | < 0.05 | S |
| Kshudhatimatra | 0.53 | 0.94 | 0.95 | > 0.05 | Ns |
| Pipasaatiyog | 1.06 | 1.59 | 1.70 | > 0.05 | Ns |

**Table 5: Results by "Dunn Multiple Comparison" Post Test**

| Symptoms | Comparison | Mean rank diff | p Value | Significance | Summary |
|---|---|---|---|---|---|
| Javoprodh | A Vs B | -9.35 | > 0.05 | Not significant | Ns |
| | A Vs C | -13.75 | < 0.05 | Significant | * |
| | B Vs C | -4.4 | > 0.05 | Not Significant | Ns |
| Daurgandhya | A Vs B | -12.53 | < 0.05 | Significant | * |
| | A Vs C | -18.38 | < 0.01 | Significant | ** |
| | B Vs C | -5.85 | > 0.05 | Not Significant | Ns |
| Swedabadha | A Vs B | -17.63 | < 0.01 | Significant | ** |
| | A Vs C | -16.2 | < 0.01 | Significant | ** |
| | B Vs C | 1.425 | > 0.05 | Not Significant | Ns |
| Kshudhatimatra | A Vs B | -10.48 | > 0.05 | Not Significant | Ns |
| | A Vs C | -8.95 | > 0.05 | Not Significant | Ns |
| | B Vs C | 1.525 | > 0.05 | Not Significant | Ns |
| Pipasaatiyog | A Vs B | -9.1 | > 0.05 | Not Significant | Ns |
| | A Vs C | -9.05 | > 0.05 | Not Significant | Ns |
| | B Vs C | 0.05 | > 0.05 | Not Significant | Ns |

**Table 6: The % relief in all 3 groups in Objective parameters**

| Objective parameters | % Relief in Group A | % Relief in Group B | % Relief in Group C |
|---|---|---|---|
| Body weight | 3.52 | 5.40 | 5.55 |
| Body Mass Index | 3.55 | 5.40 | 5.57 |
| Waist Hip ratio | 0.00 | -0.29 | -0.75 |
| Mid-Arm circumference | 1.73 | 2.09 | 3.66 |
| Mid-Thigh Circumference | 1.08 | 2.37 | 3.35 |

**Table 7: Result of Drug Therapy on Objectives parameters in Intra group comparison by" Paired t test"**

| Variable | Gr. | Mean | | Mean Diff. | % Relief | SD ± | SE ± | P | S |
|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | | | | | | |
| Body Weight | A | 68.92 | 66.50 | 2.42 | 3.52 | 0.8051 | 0.1953 | < 0.0001 | HS |
| | B | 69.88 | 66.10 | 3.78 | 5.40 | 1.0189 | 0.2471 | < 0.0001 | HS |
| | C | 70.98 | 67.04 | 3.94 | 5.55 | 1.2399 | 0.2772 | < 0.0001 | HS |
| Body Mass Index | A | 27.42 | 26.44 | 0.97 | 3.55 | 0.3384 | 0.0821 | < 0.0001 | HS |
| | B | 27.74 | 26.24 | 1.50 | 5.40 | 0.3728 | 0.0904 | < 0.0001 | HS |
| | C | 27.40 | 25.87 | 1.53 | 5.57 | 0.5138 | 0.1149 | < 0.0001 | HS |
| Waist Hip Ratio | A | 0.99 | 0.99 | 0.00 | 0.00 | 0.0085 | 0.0021 | > 0.05 | NS |
| | B | 1.00 | 1.01 | 0.00 | 0.29 | 0.0127 | 0.0031 | > 0.05 | NS |
| | C | 0.92 | 0.93 | -0.01 | 0.75 | 0.0202 | 0.0045 | > 0.05 | NS |

**Table 8: Result of Drug Therapy on Objectives parameters in Intra group comparison by" Paired t test"**

| Variable | Gr | Mean | | Mean Diff. | % Relief | SD ± | SE ± | P | S |
|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | | | | | | |
| Mid Arm Circumference | A | 36.69 | 36.05 | 0.64 | 1.73 | 0.4167 | 0.1011 | < .0001 | HS |
| | B | 37.40 | 36.62 | 0.78 | 2.09 | 0.7248 | 0.1758 | < 0.05 | S |
| | C | 37.13 | 35.77 | 1.36 | 3.66 | 0.7843 | 0.1754 | < .0001 | HS |
| Thigh Circumference | A | 62.47 | 61.79 | 0.68 | 1.08 | 0.6270 | 0.1521 | < 0.05 | S |
| | B | 62.42 | 60.95 | 1.48 | 2.37 | 0.9699 | 0.2352 | < .0001 | HS |
| | C | 63.66 | 61.52 | 2.14 | 3.35 | 1.2550 | 0.2806 | < .0001 | HS |

**Table 9: Results of Drug Therapy on Objectives parameter as Lab Investigation**

| Variable | Gr | Mean | | Mean Diff. | % Relief | SD ± | SE ± | P | S |
|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | | | | | | |
| Total Cholesterol | A | 219.04 | 205.29 | 13.75 | 6.28 | 11.0783 | 2.6869 | < 0.05 | S |
| | B | 252.03 | 213.11 | 38.92 | 15.44 | 9.7767 | 2.3712 | < 0.0001 | HS |
| | C | 219.00 | 180.68 | 38.33 | 17.50 | 8.4880 | 1.8980 | < 0.0001 | HS |
| HDL Cholesterol | A | 42.75 | 47.89 | 5.14 | 12.03 | 4.3908 | 1.0649 | < 0.0001 | HS |
| | B | 40.76 | 50.51 | 9.75 | 23.91 | 4.1639 | 1.0099 | < 0.0001 | HS |
| | C | 44.89 | 51.85 | 6.97 | 15.52 | 3.8070 | 0.8513 | < 0.0001 | HS |
| LDL Cholesterol | A | 112.18 | 101.26 | 10.92 | 9.73 | 9.1765 | 2.2256 | < 0.05 | S |
| | B | 120.74 | 96.49 | 24.24 | 20.08 | 16.5093 | 4.0041 | < 0.05 | S |
| | C | 128.46 | 114.02 | 14.44 | 11.24 | 9.7411 | 2.1782 | < 0.0001 | HS |
| VLDL Cholesterol | A | 37.29 | 32.68 | 4.61 | 12.35 | 4.3183 | 1.0474 | < 0.05 | S |
| | B | 42.47 | 35.96 | 6.51 | 15.32 | 4.2662 | 1.0347 | < 0.0001 | HS |
| | C | 40.43 | 32.85 | 7.58 | 18.74 | 5.1817 | 1.1587 | < 0.0001 | HS |

**Table 10: Results of Drug Therapy on Objectives parameter**

| Variable | Gr | Mean | | Mean Diff. | % Relief | SD ± | SE ± | P | S |
|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | | | | | | |
| Serum Triglycerides | A | 169.39 | 160.59 | 8.81 | 5.20 | 6.1054 | 1.4808 | < 0.05 | S |
| | B | 201.41 | 176.69 | 24.71 | 12.27 | 9.3396 | 2.2652 | < 0.0001 | HS |
| | C | 158.04 | 142.55 | 15.49 | 9.80 | 7.8656 | 1.7588 | < 0.0001 | HS |

**Table 11: The % relief in all 3 groups in Objective parameters**

| Objective parameters | % Relief in Group A | % Relief in Group B | % Relief in Group C |
|---|---|---|---|
| Total Cholesterol | 6.28 | 15.44 | 17.50 |
| LDL | 9.73 | 20.08 | 11.24 |
| HDL | 12.03 | 23.91 | 15.52 |
| VLDL | 12.35 | 15.32 | 18.74 |
| Serum Triglycerides | 5.20 | 12.27 | 9.80 |

**Intergroup Comparison by One-Way Analysis Of Variance Test "ANOVA Test"**

**Table 12: Effect of drug therapy in Inter Group comparisons in Objective Parameters by "One way ANOVA test"**

| Parameters | Group A | Group B | Group C | P Value | Significant |
|---|---|---|---|---|---|
| Body Weight | 2.42 | 3.78 | 3.94 | < 0.0001 | HS |
| Body Mass Index | 0.97 | 1.50 | 1.53 | < 0.0001 | HS |
| Waist to Hip ratio | 0.00 | 0.00 | -0.01 | > 0.05 | NS |
| Mid Arm Circumference | 0.64 | 0.78 | 1.36 | < 0.05 | S |
| Thigh Circumference | 0.68 | 1.48 | 2.14 | < 0.05 | S |
| Total Cholesterol | 13.75 | 38.92 | 38.33 | < 0.0001 | HS |
| HDL | 5.14 | 9.75 | 6.97 | < 0.05 | S |
| LDL | 10.92 | 24.24 | 14.44 | < 0.05 | S |
| VLDL | 4.61 | 6.51 | 7.58 | > 0.05 | NS |
| Triglycerides | 8.81 | 24.71 | 15.49 | < 0.0001 | HS |

**Tukey-Kramer multiple comparison test for parametric comparison**

**Table 13: Inter group comparison of effect of drug therapy on Body weight**

| Body weight | Mean Diff. | 95.00% CI of diff. | P Value | S. | Summary |
|---|---|---|---|---|---|
| Group A vs. Group B | -1.475 | -2.262 to -0.6875 | < 0.0001 | Hs | **** |
| Group A vs. Group C | -1.575 | -2.362 to -0.7875 | < 0.0001 | Hs | **** |
| Group B vs. Group C | -0.1 | -0.8875 to 0.6875 | > 0.05 | Ns | Ns |

**Table 14: Inter group comparison of effect of drug therapy on Body Mass Index**

| Body Mass Index | Mean Diff. | 95.00% CI of diff. | P value | S | Summary |
|---|---|---|---|---|---|
| Group A vs. Group B | -0.583 | -0.9043 to -0.2618 | < 0.05 | S | *** |
| Group A vs. Group C | -0.5833 | -0.9045 to -0.262 | < 0.05 | S | *** |
| Group B vs. Group C | -0.0002058 | -0.3214 to 0.321 | > 0.05 | Ns | Ns |

**Table 15: Inter group comparison of effect of drug therapy on Waist to Hip Ratio**

| Waist To Hip ratio | Mean Diff. | 95.00% CI of diff. | P value | S | Summary |
|---|---|---|---|---|---|
| Group A vs. Group B | 0.004122 | -0.007547 to 0.01579 | > 0.05 | NS | Ns |
| Group A vs. Group C | 0.006114 | -0.005555 to 0.01778 | > 0.05 | NS | Ns |
| Group B vs. Group C | 0.001992 | -0.009677 to 0.01366 | > 0.05 | NS | Ns |

**Table 16: Inter group comparison of effect of drug therapy on Mid Arm Circumference**

| Mid arm circumference | Mean Diff. | 95.00% CI of diff. | P value | S | Summary |
|---|---|---|---|---|---|
| Group A vs. Group B | -0.335 | -0.8382 to 0.1682 | > 0.05 | NS | Ns |
| Group A vs. Group C | -0.81 | -1.313 to -0.3068 | < 0.05 | S | *** |
| Group B vs. Group C | -0.475 | -0.9782 to 0.0282 | > 0.05 | NS | Ns |

**Table 17: Inter group comparison of effect of drug therapy on Mid-Thigh Circumference**

| Mid-thigh circumference | Mean Diff. | 95.00% CI of diff. | P Value | S | Summary |
|---|---|---|---|---|---|
| Group A vs. Group B | -0.88 | -1.637 to -0.1229 | < 0.05 | S | * |
| Group A vs. Group C | -1.45 | -2.207 to -0.6929 | < 0.0001 | HS | **** |
| Group B vs. Group C | -0.57 | -1.327 to 0.1871 | > 0.05 | Ns | Ns |

**Table 18: Inter group comparison of effect of drug therapy on Total cholesterol level**

| Total Cholesterol | Mean Diff. | 95.00% CI of diff. | P Value | S | Summary |
|---|---|---|---|---|---|
| Group A vs. Group B | -22.36 | -30.66 to -14.06 | < 0.0001 | HS | **** |
| Group A vs. Group C | -24.04 | -32.34 to -15.73 | < 0.0001 | HS | **** |
| Group B vs. Group C | -1.675 | -9.977 to 6.627 | > 0.05 | Ns | Ns |

**Table 19: Inter group comparison of effect of drug therapy on HDL Cholesterol**

| HDL cholesterol | Mean Diff. | 95.00% CI of diff. | P Value | S | Summary |
|---|---|---|---|---|---|
| Group A vs. Group B | 3.805 | 0.7003 to 6.91 | < 0.05 | S | * |
| Group A vs. Group C | 1.405 | -1.7 to 4.51 | > 0.05 | Ns | Ns |
| Group B vs. Group C | -2.4 | -5.505 to 0.7047 | > 0.05 | Ns | Ns |

**Table 20: Inter group comparison of effect of drug therapy on LDL Cholesterol**

| LDL cholesterol | Mean Diff. | 95.00% CI of diff. | P Value | S | Summary |
|---|---|---|---|---|---|
| Group A vs. Group B | -13.22 | -22.09 to -4.345 | < 0.05 | S | ** |
| Group A vs. Group C | -3.64 | -12.51 to 5.235 | > 0.05 | NS | Ns |

**Table 21: Inter group comparison of effect of drug therapy on VLDL Cholesterol**

| VLDL cholesterol | Mean Diff. | 95.00% CI of diff. | P Value | S | Summary |
|---|---|---|---|---|---|
| Group A vs. Group B | -2.44 | -5.835 to 0.9546 | > 0.05 | Ns | Ns |
| Group A vs. Group C | -3.31 | -6.705 to 0.08457 | > 0.05 | Ns | Ns |
| Group B vs. Group C | -0.87 | -4.265 to 2.525 | > 0.05 | Ns | Ns |

**Table 22: Inter group comparison of effect of drug therapy on Serum Triglycerides**

| Serum triglycerides | Mean Diff. | 95.00% CI of diff. | P Value | S | Summary |
|---|---|---|---|---|---|
| Group A vs. Group B | -15.03 | -21.29 to -8.764 | < 0.0001 | HS | **** |
| Group A vs. Group C | -5.75 | -12.01 to 0.5111 | > 0.05 | Ns | Ns |
| Group B vs. Group C | 9.275 | 3.014 to 15.54 | < 0.05 | S | ** |

## DISCUSSION

Discussion is the basic step in establishment of a proposition and help in reaching to definite conclusion. Therefore the discussion and interpretation of the research study becomes an essential and important thing for a research scholar to put their study on the scientific platform and then only it can be granted to be considered as true study.

The description of Sthoulya is found in almost all the scriptures of Ayurveda, which contain the explanation of this disease with different terminologies. Sthoulya considered as an undesirable condition of body type in Astauninditiyaadhyaya[12], on other hand it is seen as type of Dehabheda[13], as a lakshana (Symptom) of Medodosha[14], Medovahsrotasviddhalakshana[15], seen as a disease of shleshmananatmajvyadhi[16]. Due to multiple pathogenesis and various aetiologies of Sthoulya; guduchi and Mustak can be considered best acting drug due to their Broad spectrum Pharmacological activities and availability.

In Ayurveda, the action of drugs is determined on Pharmacodynamics of drug i.e. Rasa, Guna, Veerya and Vipaka along with certain specific properties called Prabhava (Karma). These drugs in combination act as antagonist to the main morbid factors i.e. Dosha and Dushya to cause Sampraptivighatan to all of the symptoms of the disease. Pharmacodynamics of drug is mentioned in Verse no. 13 in Charaka Samhitasutrasthana 26.

**Probable mode of action**

Guduchi is mentioned for Rasayanakarma, It acts over Tridosha (Vata, Pitta and Kapha), as well as Saptadhatu (Rasa, Rakta, Mamsa, Meda, Asthi, Majja and Shukra) doing Samshamanakarma naturally. That means it brings equilibrium of Dosha, Dhatu, Mala in the body by bringing equilibrium of all the vitiated Dhatus also Meda Dhatu to Sama (equilibrium) state. It is categorized in Tikta skandha which is indicated for Kleda, Medaupshoshana[17]. Guduchi and Mustak both are stated as Medhya Rasayana (brain tonic). Thus they act on Psychological factors of Obesity i.e. Stress, Depression. Its Medohara effect has been stated by Dhanvantari Nighantu[18].

Mustak is described in Lekhaneeya Mahakashaya[19] (drugs acting as scraping agents) which helps in removal of morbid accumulation and sthoulyahar action. Mustak has been stated for Deepan-Pachana Karma; as Acharya Vagbhatta is mentioned Deepan-Pachana Chikitsa[20] in the treatment of Madhyama sthoulya. Mustakalka and mustasiddhajala has been mentioned for Aam Pachana, as Aam is main pathogenesis of Sthoulya mentioned by Acharya Vagbhatta[21].



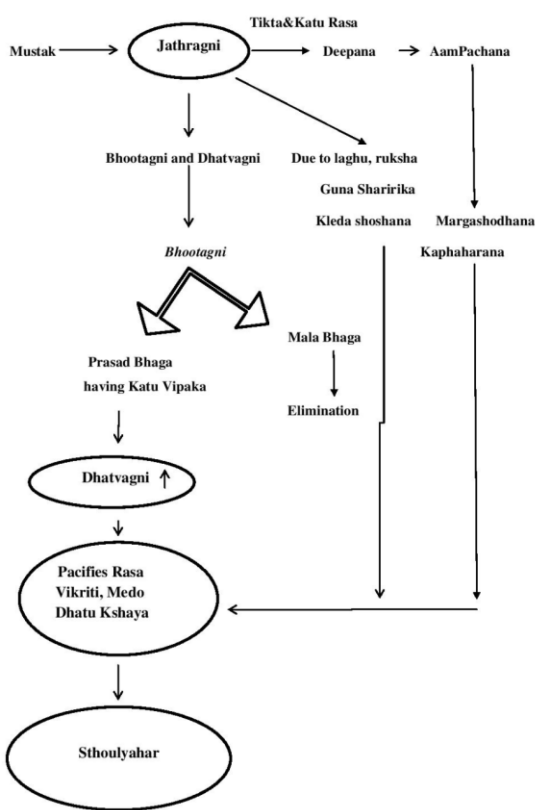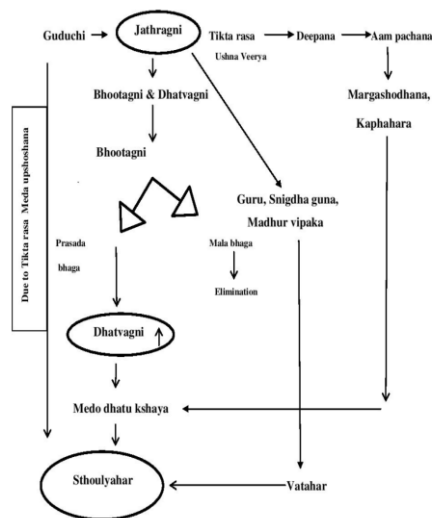**Figure 1: Probable mode of action of Mustak**



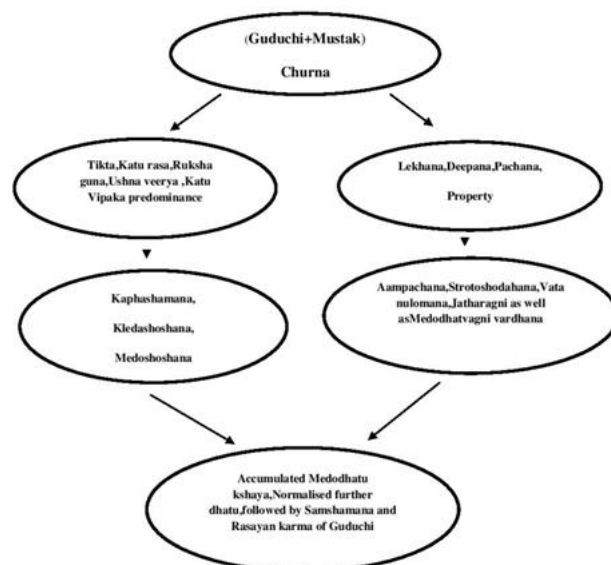**Figure 2: Probable mode of action of Guduchi**

**Figure 3: Probable mode of action of (Guduchi + Mustak)**

## CONCLUSION

Sthoulya is mainly due to vitiation of Medodhatu involving Kapha and Vatadosha producing decrement of further Dhatu. Vitiated Vata remains trapped in the Kostha and produces kshudhadhikya, which increases the gravity of the disease making Sthoulya as a Krichhasadhyavyadhi.

The trial therapy was Doshapratyanik Chikitsa, which alleviate Vata Kapha Dosha. The trial drugs were found safe no any major side effect was observed in any patient. In group B mild constipation was seen in some patients after 15 days therapy, which was managed through symptomatically. Result of the Clinical study can be concluded as, all the test drugs, showed significant result in the patients of Sthoulya. In comparison of between the groups, the drugs Mustak and Combination of Guduchi and Mustak showed almost similar significance of Sthoulyahar action in Patients of Sthoulya. Percentage wise relief were shown more in Group C i.e. combination of Guduchi and Mustak Churna than individual form of Guduchi and Mustak.

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